Bipolar scissors and clamps

NON STERILE **unsterile**

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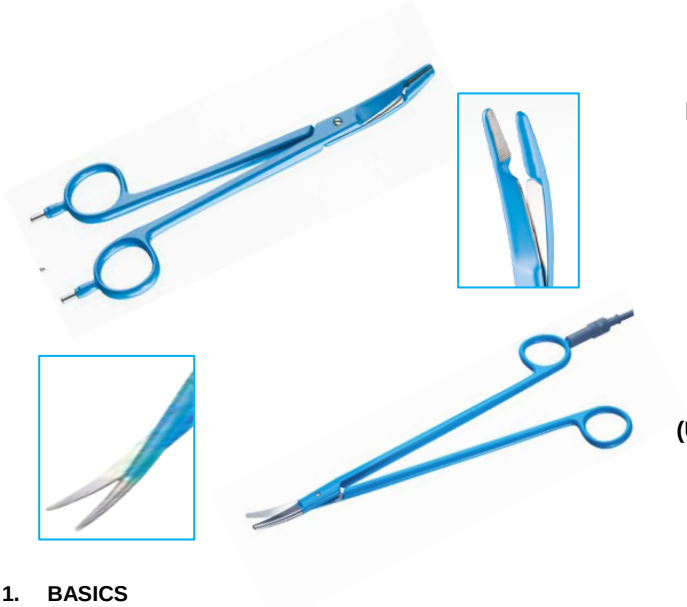

REF:

91300-xx	**R066-000200-509-R066-000200-510**
91901-xx	**R066-000250-509-R066-000250-510**
91902-xx	**R066-000340-509-R066-000340-510**
91903-xx	**R066-000450-509-R066-000450-510**
91909-27	**R067-000340-709**
91910-xx	**R067-000450-709**
91911-xx	**R070-050200-05**
91929-27	

(UMDNS: 16-206)

1. 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 requirements to be observed by the user for each product. instructions and information that 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.
Repair 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 impair performance features or safety requirements and if 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.

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. 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 21 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
NON STERILE	Information for NON sterile product		

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3. PRODUCT SPECIFIC NOTES

Our bipolar scissors and clamps, which are used in combination with an HF generator, have the required insulation and a suitable connection.
The areas of application are examination, diagnosis and / or therapy using endoscopic instruments and their accessories in various specialist areas, such as surgery, urology and gynecology, exclusively by competent, qualified personnel.

4. INTENDED USE

The working elements serve exclusively as an aid for use in HF surgery for:

- Bipolar / monopolar electrosurgical coagulation and vessel sealing by thermofusion.
- Effective, large-area hemostasis of tissue structures (open surgery and endoscopic).
- Dissection of tissue strands.

5. INTENDED USE / GENERAL INDICATION

BiTech bipolar scissors are used for cutting, dissecting and coagulating tissue.
Bipolar clamps are used to grasp, compress and coagulate or thermally seal tissue.
The fully assembled instrument (if assembly is necessary) is connected to the monopolar or bipolar output of an HF generator using a suitable cable. Only the intended parameters may be used.

Maximum output voltage of the generator Umax:
300 Vp

Suitable HF generators from the respective manufacturer:
Aesculap, Alsa, Berchtold, BOWA, Codman, Conmed, Covidien, EMC, EMED, Erbe, Hebu,Karl Storz, KLS Martin, Lamidey, Olympus, Richard Wolf, Sutter, Telea, Valleylab, Söring

Bipolar clamps
(REF 91910-14;91910-19; 91911-14;91911-19; 91929-27): 250 Vp

Suitable connection cables:
BiTech /Wave
REDA Bipolar cable (REF 91999-xx)

Suitable connection cables
Bipolar clamps
Bipolar connection cable: (Erbe /Select/Storz REF 91190-30;-50 / USA Mod. REF 91191-30;-50 / Martin Bechtold, Aesculap REF 91193-30;-50)

Instruments for electrosurgery may only be used by persons who have been specially trained or instructed for them.

CONTRAINDICATIONS

- The instrument should not be used if, in the opinion of the responsible physician, the risks for the patient outweigh the benefits.

6. INCIDENTS REPORTED IN CONNECTION WITH THE USE OF ELECTROSURGICAL SYSTEMS

- Inadvertent activation resulting in tissue damage in the wrong place and / or equipment damage.
- Fire in contact with drapes and other flammable materials.
- Alternating current paths that lead to burns at places 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 heavy bleeding.

7. APPLICATION AND SAFETY INSTRUCTIONS

Failure to observe these application and safety instructions can lead to injuries, malfunctions or other unexpected incidents.

- If electrosurgery is used on patients with cardiac pacemakers or other active implants, special requirements apply (including low RF power, patient monitoring). In any case, a cardiologist or an appropriate specialist should be consulted.
- All instruments must be completely cleaned, disinfected, sterilized and checked for functionality before they are used for the first time and before each subsequent use.
- It is very important to examine every surgical instrument for visible damage and wear, e.g. cracks, breaks or defects in the insulation before each use. In particular, areas such as cutting edges, points, keys, locks and notches, as well as all moving parts, insulation and ceramic elements must be carefully checked.
- Bipolar scissors contain high quality ceramic parts that must be handled with particular care and protected against breakage.
- Never use damaged instruments.
- Do not use in the presence of flammable or explosive substances.
- Instruments that are temporarily not used must be isolated from the patient.
- Activate HF current only if the contact surfaces are in the field of vision and have good contact with the tissue to be treated.

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Do not touch any other metallic instruments, trocar sleeves, optics or the like.
- Observe the application and safety instructions of the manufacturer of the HF surgical devices.

8. RECYCLING

Due to the product design, the materials used and the intended use, no defined limit of the maximum possible processing cycles can be set. The lifespan of the instruments is determined by their function and the careful handling of them.
Instruments for electrosurgery are naturally subject to increased wear and tear depending on the type and duration of use.

Preparation and transport
Immediately after use, rinse the instruments under cold tap water until all visible dirt has been removed; if necessary, a soft plastic brush can be used. Do not use fixing agents or hot water (> 40 ° C). Storage and transport of the instruments in a closed container to the reprocessing site.

Manual pre-cleaning

1. Soak the instruments in cold tap water for 5 minutes.
2. Brush all surfaces of the instruments under cold tap water with a soft brush until all are visible any dirt has been removed.

Automated reconditioning

Cleaning

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

1. 1 min. Pre-rinse with cold water
2. Emptying
3. 3rd min. Pre-rinse with cold water
4. Emptying
5. 5 min. Washing at 55 ° C with 0.5% alkaline or 45 ° C with a low concentration (0.3%) of enzymatic detergent
6. Emptying
7. 3 min. Neutralization with warm tap water (> 40 ° C) and neutralizer
8. Emptying
9. 2 min. Intermediate rinse with warm tap water (> 40 ° C)
10. Emptying

Disinfection

Perform mechanical thermal disinfection taking into account the national requirements with regard to the A0 value (see ISO 15883).

Drying:

Drying of the outside of the instruments through the drying cycle of the washer-/disinfector. If necessary, manual drying can also be achieved using a lint-free cloth. Dry cavities with sterile compressed air.

Manual reprocessing

Pretreatment in the ultrasonic bath:

1. The instruments are placed in an ultrasonic bath with 0.5% enzymatic cleaner and ultrasound for 15 min. At 40 ° C sonicated.
2. Remove the instruments and rinse with cold water to remove the cleaner.

Cleaning

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

1. Rinse products under cold tap water (<40 ° C) until all visible soiling has been removed. Remove stubborn dirt with a soft brush.
2. Completely immerse the products in the prepared cleaning bath. Adhere to the exposure time according to the manufacturer's instructions.
3. Manually clean the inserted instrument with a soft brush. Brush all surfaces several times.
4. Thoroughly rinse the products with fully demineralized water to completely remove the cleaning agent.

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, especially for drying cavities and channels, with sterile compressed air.

Functional testing and packaging
Perform visual inspection for cleanliness; if required, perform an assembly and functional test according to the operating instructions.
If necessary, repeat the reprocessing process until the instrument is optically clean.
Packaging has to comply with ISO 11607 and EN 868 standards for packaging for sterilised instruments.

Sterilization

The products must be sterilized in the closed state in order to ensure that the scissor blades run smoothly.
Sterilisation of the products with fractional pre-vacuum procedure (in accordance with ISO 13060 / ISO 17665) in consideration 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; maximum 137 ° C
- Holding time: at least 3 minutes; maximum 18 min.
- Drying time: at least 10 minutes.

If contamination with prions (CJD) is suspected, different national guidelines may have to be observed and longer holding times (e.g. 15 min.) Have to be observed.

Storage

Store the sterilized instruments in a dry, clean and dust-free environment. The national guidelines must be followed.

9. REPAIRS

Do not carry out repairs yourself. Service and repairs may only be carried out by appropriately trained and qualified persons. If you have any questions in this regard, contact the manufacturer or your medical-technical department.

Defective products must have gone through the entire remanufacturing process before being returned for repair.

10. REPROCESSING VALIDATION INFORMATION

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

Cleaning agent (for machine use):	Neodisher FA; Dr. Weigert (alkaline)
	Endozime Fa. Ruhof (enzymatic)
Cleaning agent (manual cleaning):	Enzol Enzym, Detergent, Johnson&Johnson
Disinfectants (manual disinfection):	Cidex OPA, Johnson&Johnson
Neutralising agent:	Neodisher Z; Dr. Weigert
Cleaning and disinfection device:	Miele G 7736 CD
	Miele insert module E 327-06
	Miele Miele MIS module E450
For details,see reports:	SMP GmbH #01707011901 (machine 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.

11. HANDLING

During transport, cleaning, care, sterilisation and storage, all surgical instruments should be handled with maximum care.
This applies particularly to blades, fine tips and other sensitive areas.

12. DISPOSAL

The disposal of the medical products, the packaging material and the accessories must be carried out in accordance with the applicable country-specific regulations and laws.

13. WARRANTY

The operator / product user is responsible for the proper cleaning, disinfection and sterilization of products. National regulations, 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.

14. 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

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