Monopolar and Bipolar forceps

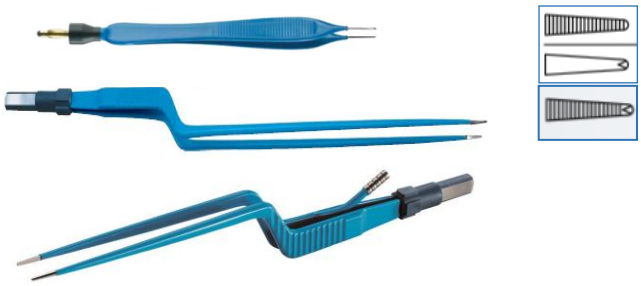
unsterile

Reda Instrumente GmbH
Gänsäcker 34
78532 Tuttlingen
(Germany)
Tel. +49(0) 7462/9445 0
Fax. +49 (0) 7462/9445 20
Email: info@reda-instrumente.de

REF:

91800-xx	**91805-xx**
91811-xx	**91801-xx**
91802-xx	**91803-xx**
91804-xx	**91300-20**
91190-10U	**91164-19U**
91227-10NU	**91228-10NU**

9110x-xx – 9119x-xx
9120x-xx – 9124x-xx
91226-0NU;-10U



(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 Manufacturer Production date
NON STERILE	Information for NON sterile product		

3. PRODUCT SPECIFIC NOTES

Our monopolare and bipolare forceps 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

Bipolar (ref. no. 80500000-81999999) and monopolar (ref. no. 89602184-89730xxx) forceps are used for grasping, dissection and coagulation of biological tissues. The fully assembled instrument (if assembly is needed) has to be connected – with the appropriate cable - to monopolar or bipolar output of an HF generator.
Only the defined parameters have to be used.

Maximum output voltage of the generator Umax:
500 Vp or. 300 Vp (depending on the type, see catalogue)
Monopolare forceps: 2000 Vp

Appropriate connecting cables for bipolar forceps::
bipolar cable / flat plug ref. No.: 91195-xx.
bipolar cable / 2-pin plug, ref. No.: 91195-xx.

Appropriate connecting cables for monopolar forceps:
monopolar cable: Erbe/Storz/Aesculap/Martin/Berchthold/Valleylab/Conmed/SoeringBowa /Bovie/Eschmann/Erbe T-Serie: REF: R329-040000-xxx; R329-050000-xxx; R329-080000-xxx; R060-040040-xxx; R060-050040-xxx; R060-080040-xxx

Instruments for electrosurgery should be used only by persons who have been specially trained in the use of such instruments.

6. CONTRAINDICATIONS

Do not use the instrument if, in the opinion of the attending physician, the risks to the patient outweigh the benefits.

Incidents which have been reported in connection with the use of bipolar systems:

- Unintended activation with resulting tissue injury on the wrong spot and/ or damage to the equipment.
- Fire in connection with surgical drapes and other inflammable materials.
- Alternating current paths leading to burns on spots where the patient or user comes into contact with components without insulation.
- Explosions caused by sparks in the proximity of inflammable gases.
- Perforation of organs. Sudden severe bleedings.
- Bipolar forceps have proved inefficient for tubular sterilisation or coagulation in the context of sterilisation and should therefore not be used for this purpose.

7. USE AND SAFETY INSTRUCTIONS

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

- When using electrosurgery in patients with pacemakers or other active implants, special requirements apply (e.g. low HF-current, patient monitoring). In any case, a cardiologist or appropriate medical specialist must be consulted.
- Before initial use and any further use, all instruments must be completely cleaned, disinfected and sterilised and their function must be checked.
- It is very important to check every surgical instrument forvisible damage and wear, such as cracks, breaks or insulation defects before each use. In particular areas such as blades, tips, notches, locking and blocking devices, as well as all movable parts, insulations and ceramic elements must be checked carefully.
- Never use any damaged instruments.
- Never use the instruments in the presence of flammable or explosive substances.
- When temporarily not in use, the instrument must be placed electrically insulated from the patient.
- Activate electrosurgical current only if the contact areas are in full view and have good contact with the tissue that needs to be treated. Do not touch any other metallic instruments, trocar sleeves, optics or similar objects during use.
- Observe the use and safety instructions of the manufacturer of the high-frequency surgical device.

Reda Instrumente GmbH
Gänsäcker 34
78532 Tuttlingen
(Germany)
Tel. +49(0) 7462/9445 0
Fax. +49 (0) 7462/9445 20
Email: info@reda-instrumente.de

Applies for monopolar mode of operation: Ensure correct application of the neutral electrode on the patient; otherwise, there is a danger of burns.

8. REPROCESSING

Due to the product design, the raw materials used and the intended purpose it is not possible to determine a precise 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.
Instruments for electrosurgery are by nature subject to increased wear depending on the type and time of use.

Preparation and transport

Remove coarse dirt from the instruments immediately after each use. Do not use fixation agents or hot water (>40°C). Storage and transport of the instruments to the reprocessing location must be ensured in a sealed container.

Machine reprocessing

Cleaning

Place the instruments in a basket on the insert module or on the inserts of the MIS module and start the cleaning process.

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

Disinfection

Machine operated thermal disinfection has to be carried out in consideration of the national requirements with regard to 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 lintfree cloth. Dry cavities by blowing with sterile compressed air.

Manual reprocessing

Ultrasonic Pre-Cleaning

1. The instrument must be inserted in an ultrasonic bath with 0.5% enzymatic cleaning detergent. Ultrasound must be applied for 15 minutes at 40°C/104°F.
2. Remove the instrument and rinse completely with cold water to remove the cleaning detergent.

Cleaning

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

1. Rinse products with cold tap water (<40°C) until all visible accumulations of dirt have been removed. Remove stuck 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. *The following step only applies to channels and the insides of tubes:* Push the brush into and out of the tubes at least six times. Rinse the tubes with VI water. Repeat the procedure.
5. Rinse the products thoroughly with DI water to remove the cleaning agents without residue.

Disinfection

Prepare a disinfectant bath according to the instructions of the disinfectant manufacturer. Place the instruments in the disinfectant bath and observe the specified residence time. Rinse the products very thoroughly with DI water to remove the disinfectant without residue.

Drying

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

Reda Instrumente GmbH
Gänsäcker 34
78532 Tuttlingen
(Germany)
Tel. +49(0) 7462/9445 0
Fax. +49 (0) 7462/9445 20
Email: info@reda-instrumente.de

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.

CLARIS non-stick bipolar forceps
The polished precious metal forceps tips of the CLARIS bipolar forceps may tarnish similar to silver. This does not impair function.

Bipolar forceps with irrigation
The enclosed wire insert should be always inserted in the irrigation channel, except during use and cleaning, in order to prevent clogging. The irrigation channel must be rinsed very thoroughly during cleaning. The passage has to be checked after cleaning.

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; 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, differing national guidelines are to be followed and longer holding times (i.e. 15 min.) may apply.

Storage
Sterilised instruments must be stored in a dry, clean and dust-free environment. The applicable national guidelines must be followed.

9. REPAIRS
Never attempt to perform repairs yourself. Service and repair work must only be performed by persons trained and qualified accordingly.
If you have any question regarding these matters, contact either the manufacturer or your medico-technical department.

Defect products must pass the complete reprocessing 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
Disposal must be carried out in accordance with the respective applicable local and national laws and regulations.

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 exclusively supplies tested and faultless products to its customers.
All products are designed and manufactured to comply with maximum quality requirements. We refuse any liability for products which have been modified as compared to the original product, misused or handled or used improperly.

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
- 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

REDA INSTRUMENTE GMBH

Reda Instrumente
Reda Instrumente GmbH
Gänsäcker 34
78532 Tuttlingen
(Germany)

Tel. +49(0) 7462/9445 0
Fax. +49 (0) 7462/9445 20
Email: info@reda-instrumente.de