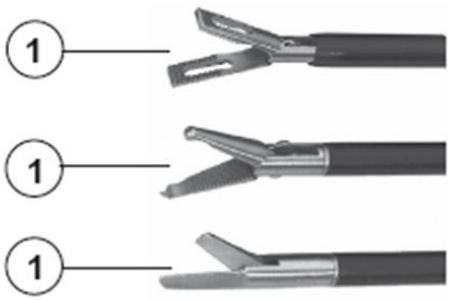
REDA INSTRUMENTE GMBH	**Coagulation forceps for the Electrosurgery** NON STERILE **unsterile**	**Reda Instrumente GmbH** **Gänsäcker 34** **78532 Tuttlingen** (Germany) Tel. +49(0) 7462/9445 0 Fax. +49 (0) 7462/9445 20 Email: info@reda-instrumente.de



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(UMDNS: 16-206)

1. BASICS

It is likely that all requirements and specific information will be acknowledged. The products for conscious use will soon not be needed. The content usage information that may be attached to the necessary content must be observed.

Take, drop yourself, or wonder, please ask before you buy the products.

These instructions for use cannot reflect the training, implementation or the state of the art in user acquisition. We establish that the legal provisions, standards and contracts (e.g. of the RKI or AKI) are known beforehand and that the user has rights and information that are relevant to our products and which are relevant to each product. Reasons for these rights and the dangers arising from non-compliance are in the legal provisions and in the rights.

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		Symbol for manufacturer
	ATTENTION! Important instructions!	NON STERILE	Information for NON sterile product
CE 0297	CE-Mark and registration number of the Notified Body DQS Medizinprodukte GmbH August-Schanz-Straße 21 60433 Frankfurt, Germany		Follow the instructions You can also find useful information on the website www.a-k-i.org "Instrument reprocessing done right"
LOT	Batch number		

3. PRODUCT SPECIFIC NOTES

Our barrel instruments with a handle basically consist of a handle, a shaft and an insert. Instruments that are used in combination with an HF generator have the required isolation and a suitable connection.
The areas of application are examinations, 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 aids 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

The detachable coagulation forceps CLASSIC, ORBITARIS, POWERGRIP, POWERGRIP 3.0, SLIMLINE and Mithras have been designed for use in minimally invasive surgical procedures, in particular in laparoscopy. The instrument has to be inserted through a trocar sleeve with the appropriate diameter or natural body openings.
The coagulation forceps are intended to be used for dissection, grasping or cutting of biological tissue. 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 has to be used. Cutting or coagulation current is activated by a foot-switch that is part of the electrosurgical generator.

6. CONTRAINDICATIONS

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

- Not intended to be used for tubal sterilization or tubal coagulation following sterilization.

Incidents that have been reported in connection with the use of electrosurgical systems

- Unintended activation with resulting tissue injury in the wrong location 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.

7. USE AND SAFETY INSTRUCTUCTIONS

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 for visible 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 he high-frequency surgical device.

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

8. ASSEMBLY AND OPERATION

The individual components of a dismantling instrument are

- handle (with or without lock)
- shaft tube
- Use (pliers or scissors)
- Union nut

The assembly is described in the following chapter and must be checked before each use. Before the intervention, the union nut must be tightened and the function of the instrument checked by operating the handle.

Damaged instruments must never be used. They must be sent to the manufacturer for repair immediately. You are not allowed to attempt repairs yourself.

Once correctly assembled, the device may be used in either the right or the left hand.

To close jaws: compress (grip) handle.

To open jaws: release (grip) handle.

Cutting or coagulation current is activated by a foot-switch that is part of the electrosurgical generator.

Important!
Before sterilization:
Tension cracks are avoided and unhindered access of steam is guaranteed if the union nut is loosened with at least ½ turn.

The opening and closing of the jaws must be checked.
The rotatability of the shaft tube or the jaw part by means of the rotary knob must also be checked. If the shaft tube or the jaw part cannot be rotated, dismantle the forceps / scissors insert and reassemble it. The function must then be checked again.

A. FUNCTION OF THE WHEEL

The insert (pliers or scissors) is turned to a certain position with the rotary knob. Depending on the type of handle, the work can be made easier by locking the lock.

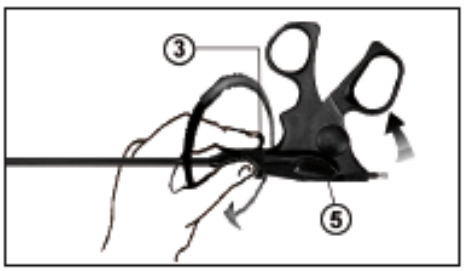
Attention!
The product is intended for use with high frequency current with a maximum recurring peak voltage of up to 2.0 kV. Forced and spray coagulation above 2.0 kV are not permitted.
The product is only suitable for short-term coagulation of small bleeds.

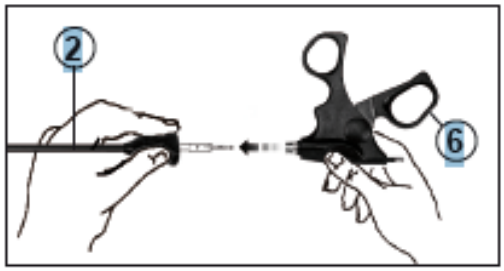
B. DISMANTLING

The pliers and scissors must be dismantled for cleaning, as closed below.
Attention: In the case of handles with a lock, this must be expected or unlocked.

C. DISASSEMBLY OF THE STEM TUBE WITH MOUNTING PART FROM THE HANDLE:

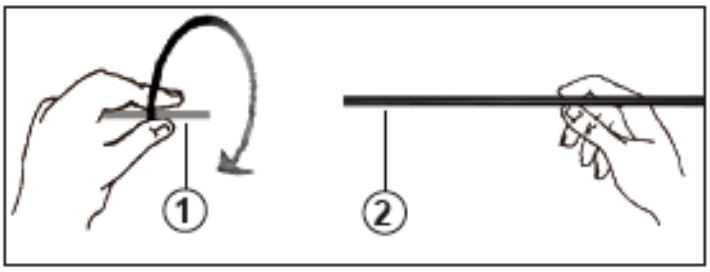
The shaft tube (2) is removed with the jaw part by unscrewing the fixing knurled nut (3) in the direction of the arrow. The movable handle leg (6) moves into an axial position when the shaft tube (2) is pulled out of the handle (5).





D. DISASSEMBLY OF THE JOINT PART FROM THE STEM TUBE:

Turn the jaw part (1) in the direction of the arrow and remove it from the shaft tube (2) (bayonet lock).



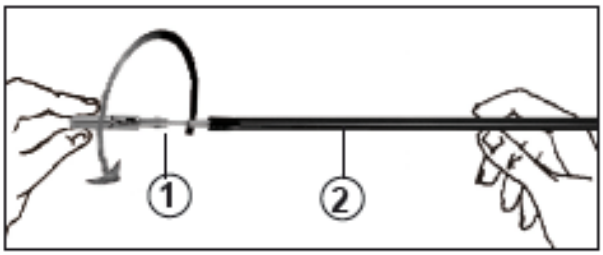
The dismantled instrument then consists of three parts: jaw part, shaft tube, handle. Instruments with metal handles are disassembled in the same way.

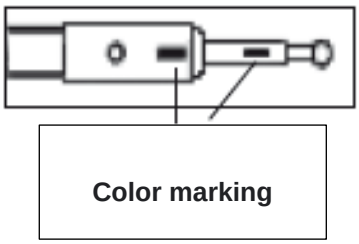
E. ASSEMBLY

Before assembly, all parts must be carefully dried inside and out.

F. ASSEMBLY OF THE JOINT INTO THE STEM TUBE

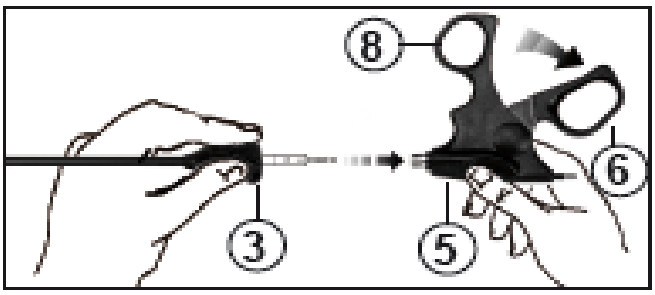
Push the jaw part (1) into the shaft tube (2) so that the guides come to rest in the grooves. Lock the jaw part by turning it as far as it will go in the direction of the arrow. The color markings at the end of the pipe then run in a line.



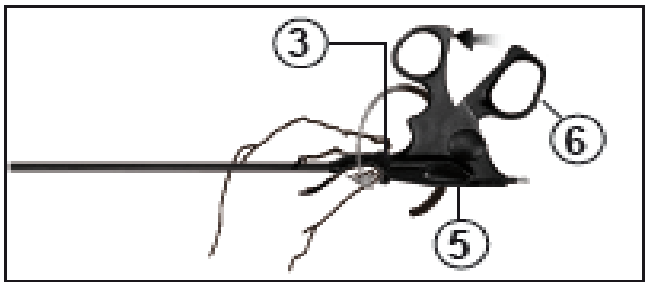


G. ASSEMBLY OF THE STEM TUBE WITH THE JOINT INTO THE HANDLE A:

Caution: It is essential to ensure that the fixed handle (8) is pointing upwards and the movable handle (6) is fully open in the axial position.



Insert the shaft tube with the jaw part into the handle (5) in the direction of the arrow. The tube part and the assembled jaw part can only be inserted into the handle if the jaw part and tube are correctly placed one inside the other. Note the color marking at the end of the pipe!
Turn the knurled nut (3) in the direction of the arrow and tighten slightly.
The pliers part is correctly engaged when, when the knurled nut is tightened, the movable handle leg (6) of the handle moves back from its axial position into the basic position.



Attention: Please make sure that handles without lock, with white marking (white cover) are primarily intended for scissor jaw parts. This makes it easier for the surgeon to find it quickly on the instrument tray.

H. FUNCTIONAL CHECK

After assembly, the pliers and scissors must be checked for their function. To do this, the opening and closing of the pliers and the rotatability must be checked:
If the jaws cannot be moved, the forceps or scissors must be dismantled again, as described in Chapter 10, and reassembled according to Chapter 10 F. Only release functioning pliers and scissors for sterilization or use.
With scissors, PE pliers and punches, the cut surfaces of the branches must be sharp and undamaged. Jaw parts with defective cut surfaces and corroded parts must be replaced.

9. BASIC WARNINGS AND PRECAUTIONS

The products are delivered UNSTERILE! The packaged products are marked accordingly.
After receiving the products, check their identity, completeness, integrity and function.

Before any instruments are used, they must be examined for breaks, cracks, deformations, damage and functionality. Areas such as cutting edges, points, keys, locks, notches and all moving parts must be checked particularly carefully. Worn, corroded, deformed, porous or otherwise damaged instruments must be sorted out.

The attending physician and all other persons involved in the handling of the products are responsible for having the appropriate product knowledge based on the latest technology standards within their area of activity. This enables the correct handling of the products and prevents health or safety risks for patients, users or third parties.
The relevant product catalogs, videos, technical specifications, instructions from medical product advisers, working groups, seminars, specialist courses, publications, etc. serve as sources of information for the products. A corresponding product training - including the handling of the products must be carried out prior to clinical use

The indications for use for the products represent a group of standard information that can be adapted to individual needs and situations that arise according to the skills, experience and diagnosis of a legally qualified medical user. The attending physician is responsible for the correct selection of the patient, the assessment of the indication and the choice of the instrument.

The correct selection of products is extremely important. The correct size of the drill, milling cutter or thread cutter to be used should be determined individually with the nature of the bone and depending on the expected load. This can be determined by assessing the functional needs of the patient and their anatomy. An implant must be implanted in the correct anatomical position in accordance with recognized standards for internal fixation. Application errors in the selection of the correct component can lead to loosening, bending or breakage of the instrument and / or bone. Also note other general scientific documents with detailed indications regarding the selection, the correct implantation site and the selection and implantation of the correct instruments. The products must be handled and stored carefully. Damage or scratches on the rotating equipment can significantly impair the strength and fatigue resistance of a product. The attending physician should discuss in detail with the patient the expected outcome of the use of the products. Particular attention should be paid to a post-operative consultation and the need for regular medical check-ups. The patient must be instructed in proper post-operative hygiene and should be instructed to inform the treating physician immediately of any unusual changes in the surgical area. The patient should be constantly monitored if a change in the operating area is noticed.

After contact with or use on patients with Creutzfeldt-Jacob disease (CJD) or its variants, we decline any responsibility for the use! In this context, please note that you may have contaminated the unused instruments in the trays.

10. 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.

11. RETURNS

Any return of products may only be sent back to us after a clearly visible disinfection / sterilization (appropriate packaging with sterile indicators, decontamination certificate, etc.).
The relevant hygiene and industrial premises regulations must be observed.

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

12. PROCESSING, CLEANING, DISINFECTING AND STERILIZING THE PRODUCTS

A. GENERAL PRINCIPLES

All products must be cleaned, disinfected and sterilized before use. The product packaging and protective transport packaging are generally not suitable for sterilization and must be removed before reprocessing! Effective cleaning and disinfection is an essential prerequisite for efficient sterilization.
As part of your responsibility for the sterility of the instruments during use, please ensure that only sufficiently device and product-specific validated procedures are used for cleaning / disinfection and sterilization, that the devices used (WD, sterilizer) are regularly maintained and checked and that the validated parameters are adhered to in each cycle.
Please also observe the legal provisions applicable in your country as well as the hygiene regulations of the doctor's practice or hospital. This applies in particular to the different requirements with regard to effective prion inactivation.

B. CLEANING AND DISINFECTION

Basics

or the cleaning and disinfection of the drilling instruments, milling cutters and components, a mechanical process (RDG (cleaning and disinfection device) / disinfector) should be used if possible. A manual process - also using an ultrasonic bath - should only be used if a machine process is not available due to its significantly lower effectiveness[1].

[1] The use of a manual cleaning and disinfection process must be secured by an additional product and process-specific validation under the responsibility of the user.

Machine cleaning / disinfection (RDG)

When selecting the WD, make sure that

- that the WD has a tested effectiveness (e.g. DGHM or FDA approval or CE marking in accordance with DIN EN ISO 15883),
- that if possible a tested program for thermal disinfection (at least 5 min at 90 ° C or A0 value> 3000) is used (with chemical disinfection there is a risk of disinfectant residues on the instruments)
- that the program used is suitable for the instruments and contains sufficient rinsing cycles,
- that suitable water (e.g. Aqua purificata / Aqua purificata valde) is used for rinsing, and that the air used for drying is filtered and thus does not reduce the hygiene status at this point,
- that the WD is regularly serviced and checked.

When selecting the cleaning agent system used, it is important to ensure that

- that this is basically suitable for cleaning the instruments,
- that - if thermal disinfection is not used - a suitable disinfectant with tested effectiveness (e.g. VAH / DGHM or FDA approval or CE marking) is also used and that this is compatible with the cleaning agent used and
- That the chemicals used are compatible with the instruments and components.

The concentrations specified by the manufacturer of the cleaning agent and, if applicable, the disinfectant must be observed.

Procedure:

1. Place the instruments in the WD. Make sure that the instruments and components do not touch each other and that they are aligned so that no large amounts of liquid can remain on the products.
2. Start the program.
3. Remove the products from the WD at the end of the program.
4. Check and pack the products as soon as possible after removal (see chapter "Control" and "Packaging", if necessary after additional drying in a clean place).

Evidence of the fundamental suitability of the instruments for effective machine cleaning and disinfection was provided by an independent, accredited test laboratory using the "RDG G 7836 CD" (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the cleaning agent " Neodisher mediclean forte "(Dr. Weigert GmbH & Co. KG, Hamburg). The procedure described above was taken into account here.

Holes:
When pre-cleaning, rinse the holes at least 3 times using a disposable syringe (at least 10 ml, with larger diameters correspondingly more volume).

C. CONTROL

Check all instruments and components for damage and soiling and separate out damaged and soiled products. Instrument oils must not come into contact with the instruments.

D. MAINTENANCE

Put the disassembled instruments back together.

If possible, instrument oils will not be provided. If an insert is changed, it will only be that only instrument oils (white oil) are used which - below the maximum sterilization temperatures used - are used for steam sterilization and have a possible biocompatibility.

E. PACKAGING

Sort the cleaned and disinfected products into the sterilization trays and pack them in single-use sterilization packaging (single or double packaging) and / or sterilization containers that meet the following requirements:

- according to DIN EN ISO / ANSI AAMI ISO 11607 and EN 868-2 to -10
- suitable for steam sterilization (temperature resistance up to at least 137 ° C (279 ° F), sufficient steam permeability)
- Sufficient protection of the instruments and sterilization packaging from mechanical damage
- regularly maintained according to the manufacturer's specifications (sterilization container)

F. STERILIZATION

Only the sterilization processes listed below are to be used for sterilization; other sterilization methods are not permitted.

Steam sterilization:

- Fractional vacuum process / pre-vacuum process or gravitation process2 (with sufficient product drying)
- Steam sterilizer according to DIN EN 13060 or DIN EN 285
- validated according to DIN EN ISO / ANSI AAMI ISO 17665 (valid picking and product-specific performance assessment)
- maximum sterilization temperature 134 ° C (273 ° F; plus tolerance according to DIN EN ISO / ANSI AAMI ISO 17665)
- Sterilization time (exposure time at the sterilization temperature) at least 5 min3 at 132 ° C (270 ° F) / 134 ° C (273 ° F)

[2] The less effective gravitation method may only be used if the fractional vacuum method / pre-vacuum method is not available.
[3] or max.18 min (prion inactivation)

Evidence of the fundamental suitability of the instruments for effective steam sterilization was provided by an independent, accredited test laboratory using the steam sterilizer "Systec V-150, Systec Labor-Systemtechnik,
Wettenberg "using the fractional vacuum process and the gravitational process. The procedure described above was taken into account here.

The flash sterilization process is generally not permitted. In addition, do not use hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization, or plasma sterilization.

ATTENTION! STERILIZATION IS NOT A REPLACEMENT FOR CLEANLINESS!

G. STORAGE

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

Operating, storage and transport conditions

Operating conditions	+10°C bis +40°C, 30% bis 75% rel. Feuchte, Luftdruck 700 hPa bis 1060 hPa
Storage and transport conditions	-20°C bis +40°C, 10% bis 90% rel. Feuchte, Luftdruck 700 hPa bis 1060 hPa

H. MATERIAL RESISTANCE

When choosing cleaning agents and disinfectants, please ensure that they do not contain the following components:
organic, mineral and oxidizing acids

- stronger alkalis (pH> 11 not permitted, mildly alkaline cleaners recommended)
- organic solvents (alcohols, acetone, ...), petrol
- halogenated hydrocarbons, chlorine, iodine
- ammonia

All instruments, sterilization trays and sterilization containers may only be exposed to temperatures not higher than 137 ° C (279 ° F)!

I. MULTIPLE PROCESSING

If an instrument has been removed from the sterile packaging or the instrument tray and, according to the previous descriptions, not used and not discarded or sorted out for other reasons, it can be reprocessed. This also applies to instruments that have already been reprocessed once or several times. However, please note the restriction from Section 12, last paragraph, regarding Creutzfeldt-Jacob disease (CJD).
Repeated processing does not result in any dimensional changes and, according to our current knowledge, no material changes. However, we would like to point out that due to the accumulation of detergent residues, the biological compatibility of the instrument can no longer be guaranteed. This is the responsibility of the user to monitor.

Shaft tubes:
When pre-cleaning, rinse the shaft tubes at least 3 times using a disposable syringe (at least 10 ml, with larger diameters correspondingly more volume).

13. WARRANTY

Safety note: The responsibility for the proper cleaning, disinfection and sterilization of products lies with the operator / product user. National regulations, including restrictions, must be observed.

Reda 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.
Reda GmbH, as the distributor of the products, excludes any warranty claims and assumes no liability for direct or consequential damage caused by:

- improper use
- improper use, application or handling
- improper preparation and sterilization
- improper maintenance and repair
- Failure to observe the instructions for use

14. NORMS - REFERENCES

- AKI1 - Guide "Instrument reprocessing done right"
- RKI2 - recommendation: "Hygiene requirements for the reprocessing of medical products"
- DIN EN 285 large steam sterilizers
- DIN EN 13060 small steam sterilizers
- 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

1 AKI: Instrument reprocessing working group
2 RKI: Robert-Koch-Institut

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