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HF electrodes - monopolar

unsterile

(UMDNS: 16-860)

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.

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 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.

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!

B INFORMATION AND SYMBOLS ON LABELS

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

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1. Warranty

We give a full guarantee in the event of production or quality defects. In the case of obvious defects caused by incorrect production or the use of defective materials, the products will be revised or replaced free of charge.
In the event of damage due to improper handling, such as mechanical impact, fall, overload, etc., the guarantee is excluded. If repairs are carried out by unauthorized persons, any guarantee claims will expire.

2. DESCRIPTION and product-specific information

Our products can be a single / spare part or a complete instrument. These are products that are intended for multiple use. Some of the instruments can be dismantled, please note the information in these instructions. The products are medical products within the meaning of national and international laws for products in human medicine.

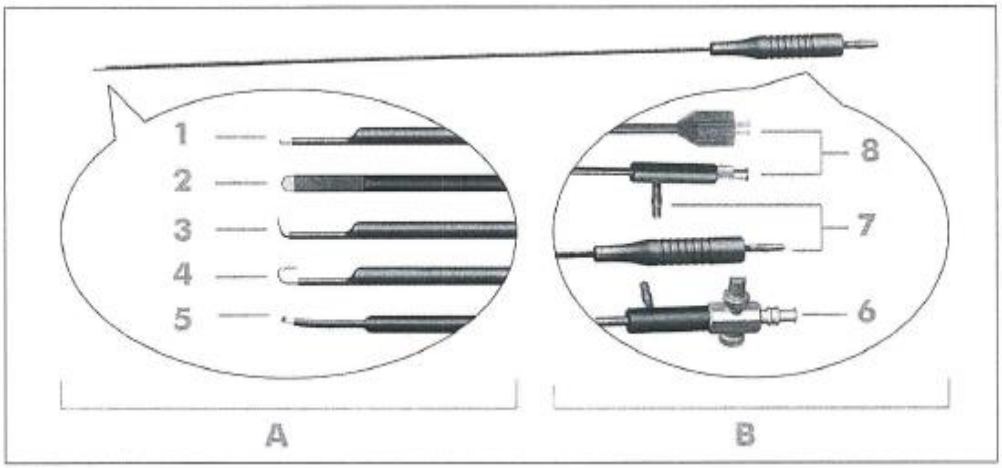

Figure: Monopolar electrodes

A	Electrode tip
B	Electrode handle
1	Button electrode
2	Spatula electrode
3	Hook electrode 90 °
4	Round hook electrode
5	Needle electrode
6	Trumpet valve with LL connection
7	Contact pin for HF connection
8	LL connector

3. Basic information

- Follow the instructions for use exactly
- Clean and sterilize brand new instruments before using them for the first time,
- Prepare used instruments promptly
- Open the joints of the instruments before reprocessing
- Disassemble instruments as much as possible for reprocessing
- Check the compatibility of patients with pacemakers for HF radiation
- Do not use explosive substances during the operation.
- To avoid carbonation of the tissue, the working voltage of the HF generator must not exceed 650 Vp.
- Do not place the instrument on the patient.
- Only coagulate if the contact surfaces of the instrument are visible.
- Do not touch any other metallic objects during coagulation.
- Use suitable HF generators.
- Use only original accessories.
- Do not use or repair damaged instruments.
- Take out of the packaging carefully

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.

4. Intended use / indication

In monopolar application technology, a current flows from the active electrode through the biological tissue to the neutral electrode. The HF generator serves as a voltage source for the high-frequency current. The electrical circuit is closed by the supply line to the surgical handle, to the active electrode and to the patient as well as to the neutral electrode and its connection cable.

HF instruments and their accessories are intended for minimally invasive surgical (mic) interventions in diseases of the abdominal cavity. An optical instrument is inserted for diagnosis and further instruments with various attachments or jaws (forceps, scissors, needle holders) for therapy or surgery. With the provided HF connection, these instruments can be used to coagulate tissue.

The surgically invasive HF instruments are inserted into the abdominal wall through the surface of the skin through an approx. 0.2 - 2 cm long incision in order to perform an operative function in the abdominal cavity. The pliers are used for holding and joining under sight, the scissors for cutting under sight. The attachments are interchangeable (see instructions for use). The application is limited to a professionally trained group of users and only permitted to trained medical professionals, especially surgeons.

The loop instruments are used to grasp and remove e.g. polyps or other tissue changes. These instruments are used surgically invasively and invasively in connection with body orifices.

5. Scope of application

The following overview shows areas of application for the different electrodes.

+ compatible
- incompatible

Electrode	Coagulation	Cutting	Vaporising
Button electrode R060-xxxxxx-001 R061-xxxxxx-001 R062-xxxxxx-001 R063-xxxxxx-001 R064-xxxxxx-001	+	-	+
Round hook electrode R060-xxxxxx-002 R061-xxxxxx-002 R062-xxxxxx-002 R063-xxxxxx-002 R064-xxxxxx-002	+	+	+
Hook electrode R060-xxxxxx-003 R061-xxxxxx-003 R062-xxxxxx-003 R063-xxxxxx-003 R064-xxxxxx-003	+	+	+
Spatula electrode R060-xxxxxx-004 R061-xxxxxx-004 R062-xxxxxx-004 R063-xxxxxx-004 R064-xxxxxx-004	+	+	+
Needle electrode R060-xxxxxx-005 R061-xxxxxx-005 R062-xxxxxx-005 R063-xxxxxx-005 R064-xxxxxx-005	+	+	+

6. Technical data

Operating conditions

Designation	value
Working voltage	200 - 650 Vp
temperature	≤135 °C

Lager- und Transportbedingungen

Designation	value
temperature	-30°C – +40°C
Relative humidity	≤90 %
Air pressure	700–1200 hPa

Product life

≤50 Cycles and ≤2 Years

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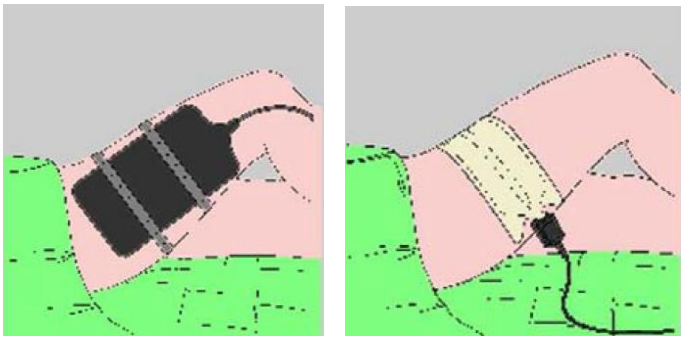
7. Connection to the HF device in monopolar mode

It is essential to examine instruments for damage (insulation)

First, the neutral electrode is attached to the patient, if possible to the upper arm or thigh. The skin must be free of hair and grease at this point. Distribute the conductive gel evenly on the neutral electrode. The current paths in the patient's body should be short and run in a diagonal direction. Never let current paths run across the body and under no circumstances through the thorax.



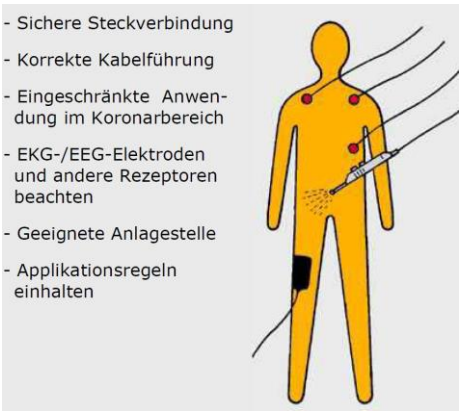
The following conditions must be met:
Full-surface and permanent contact of the neutral electrode, i.e. selection of the largest possible neutral electrode

- Application with the full active surface of the neutral electrode
- Surface of the neutral electrode free of dirt and residues
- Prohibition of contact with protruding bones
- Prohibition of plant on scar tissue
- Prohibition of installation over implants
- Guarantee of permanent application (rubber bands)
- Shave heavy hair without using alcohol
- Neutral electrode as close as possible to the operating field
- Prevent moisture inclusions!

The patient must be isolated from all electrically conductive parts. Ground the operating table, place the patient on a dry, electrically insulating surface. Avoid skin-to-skin contact. Put in dry gauze. HF cables must never lie directly on the patient's skin. Do not lay RF cables in loops. Then connect the instrument or handle to the electrode for coagulation and connect it to the HF generator. Then the neutral electrode, foot switch and electrode are connected to the HF device using the HF cable provided.
To avoid image interference on the monitor, HF cables must not be run directly parallel to camera cables. Access to the operating field is via a trocar.

When attaching the neutral electrode, the following must be observed:

- Flawless technical condition of the neutral electrode
- Safe plug connections
- Correct cable routing, i.e.
- Cable routing without touching the patient
- Cable length as short as possible
- Cable routing without loops
- Cable routing without contact with other lines, e.g. ECG lines
- Do not lay the patient on the cable
- Limited use in the coronary area
- Pay attention to ECG / EEG electrodes and other receptors
- Correct positioning of the neutral electrode
- Observe the application rules
- No damage to the insulation



8. Contraindications

- not for use in the area of the central nervous and circulatory system
- Health conditions that inhibit the healing process
- Impairment of the blood supply
- Previous infections, febrile infections
- Further illness histories known to the user, which negatively influence the healing process, e.g. thrombosis, Parkinson's disease, MS, progressive muscular dystrophy
- Pacemaker patients
- Metal implants
- Not applicable to hemophiliacs
- on or over severe inflammation

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9. Possible dangers

- Risk of electric shock
- Technical defects
- Unwanted high frequency burns
- Operating errors
- Defective accessories
- Ignition of flammable liquids and gases
- Dangers from improper combination with other devices

10. Warning notices

The products may only be used in combination with Reda accessories and only by clinically trained specialists will.

The **output power** of the HF device may only be set to the value absolutely necessary for the intervention.

If the usual coagulation performance is not achieved despite the standard setting of the HF device, never without prior testing increase the output power of the device. The following must be checked in detail: perfect contact of all HF plugs and cables, Functioning of the foot switch or the finger switch on the handle, insulation of the HF cables, the instrument and nausea of the distal end of the active electrode.

Before the start of the operation, the interference-free signaling is activated by pressing the yellow button (CUT) and the blue button (COAG).

Check the transmission (e.g. without noise) of the monitors. Endogenous burns are burns that cause burns due to high current density in the patient's tissue. Causes can include: The patient inadvertently receives contact electrically conductive parts. If HF cables come into direct contact with the skin, capacitive currents can cause burns.

Endogenous burns are burns caused by high current density in the patient's tissue. causes can include: The patient unintentionally comes into contact with electrically conductive parts. In the event of direct skin contact with HF

Cables can cause burns by capacitive currents.

Exogenous burns are burns from the heat of ignited liquids or gases. There are also explosions possible. Causes can be: inflammation of skin cleaning agents and disinfectants, inflammation of Anesthetic gases etc ...

Heart pacemakers can be damaged by HF currents. Consult a cardiologist prior to the procedure. Never perform outpatient interventions with HF current on patients with cardiac pacemakers.

The operation itself can cause infections, regardless of the instruments used. The HF electrodes are used in conjunction with HF devices (monopolar), trocars / trocar sleeves and corresponding endoscopes.

11. Visual inspection

Before and after each use, the instrument and its accessories must be checked for damage, loose or missing parts, sharp edges and rough surfaces. The insulation of the HF cable and the shaft tubes must be checked and replaced if necessary. All labels must be legible and complete.

12. Use

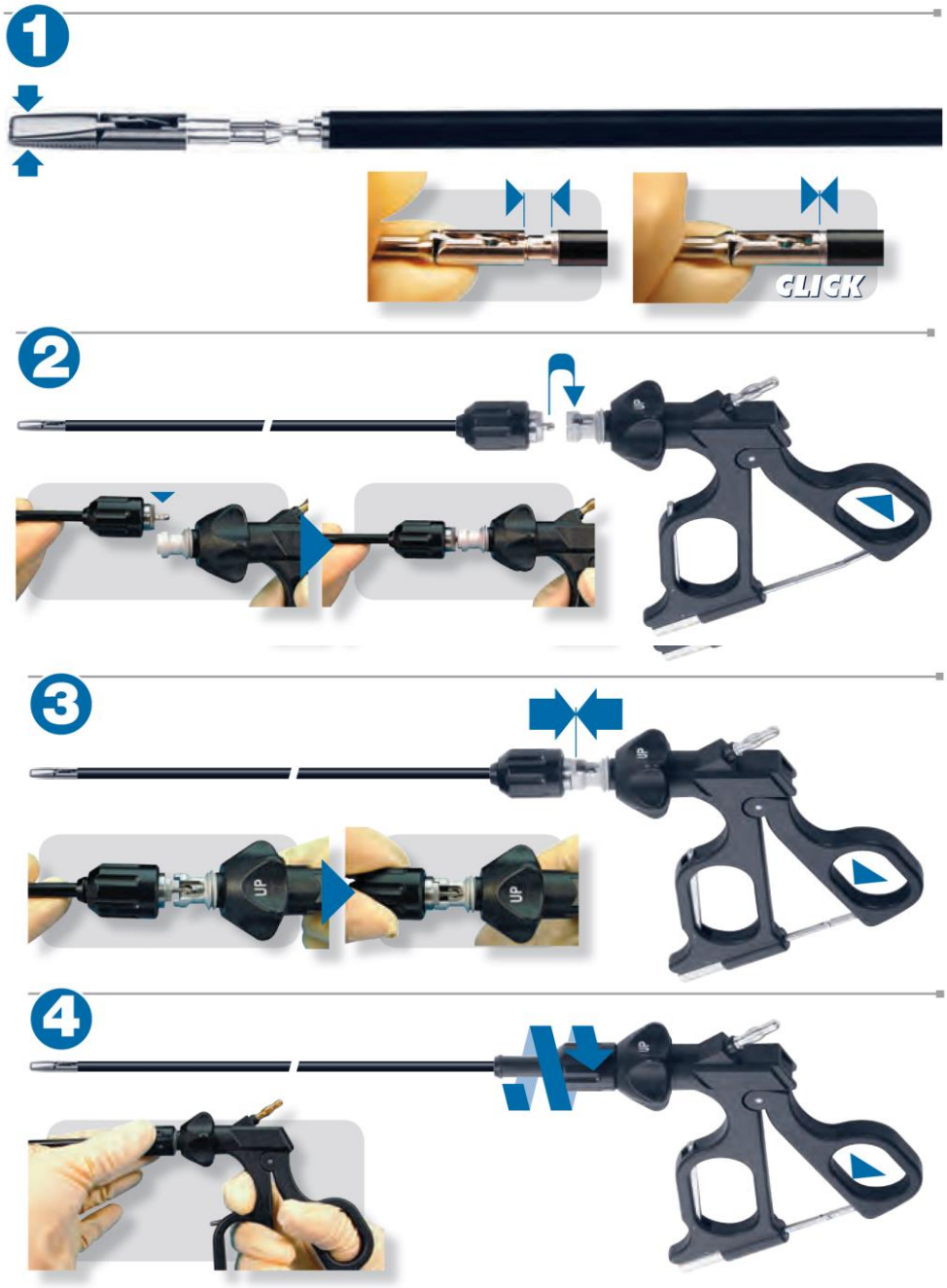
The product is intended for use with high frequency current with a maximum recurring peak voltage of up to 2.0 kV. Forced and spray coagulation above 2.0 kV are not permitted.
The product is only suitable for short-term coagulation of small bleeds.
Excessive force can damage or break the products.
Due to the required small dimensions, the stability of the product is only limited.
Check the product for damage and completeness immediately after use. No missing parts may remain in the patient!

The products are compatible with:

Monopolar connection cables:
Erbe/Storz/Aesculap/Martin/Berchthold/Valleylab/Conmed/SoeringBowa/Bovie/Eschmann/Erbe T-Serie

HF-Generators:
Erbe, Martin, Storz, Select, Olympus, Valeylab, Aesculap, Berchthold

13. Montage



14. Preparation and maintenance

The instrument must be cleaned of all blood and other residues with a pH-neutral cleaning agent after each use. Use only soft brushes and sponges for this. Particular care must be taken with the shaft tube and the areas where dirt and residue can accumulate.
Do not use silicone or oil based greases.
Cleaning aids (brushes, sponges, cloths, etc.) should be cleaned and disinfected daily. The sterilization equipment must be carefully calibrated and maintained. After cleaning, the instrument and the HF cables must be carefully checked for cleanliness and damage.
See reprocessing instructions!

15. Operating, storage and transport conditions

Operating conditions	+10°C bis +40°C, 30% bis 75% rel. Humidity, Air pressure 700 hPa bis 1060 hPa
Storage and transport conditions	-20°C bis +60°C, 10% bis 90% rel. Humidity, Air pressure 700 hPA bis 1060 hPa

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

16. Repair

- 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.

17. 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. Reda Instrumente GmbH defines the reusability of the instruments for a maximum of 50 reprocessing cycles, but not longer than two years.

18. Disposal

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

19. Standards - 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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