HF- Electrodes bipolar

unsterile

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R067-050340-001;
R067-050340-002
R067-050340-003
R067-050340-004
R067-050340-005
R068-030340-003
R068-030340-010
R068-030340-012
91176-19
91177-20
91178-14

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	CE 0297	CE-Mark and registration number of the Notified Body DQS Medizinprodukte GmbH August-Schanz-Straße 21 60433 Frankfurt, Germany
⚠	ATTENTION! Important instructions!		Temperatur -30°C – +40°C
LOT	Batch number		Follow the instructions You can also find useful information on the website www.a-k-i.org "Instrument reprocessing done right"
NON STERILE	Information for NON sterile product		Symbol for manufacturer

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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

Bipolar HF instruments are used to coagulate tissue. They must be connected to the bipolar output of an HF generator using a suitable bipolar cable. 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.

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 be 650 Vp exceed.
- 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.
- Only use original accessories.
- Do not use or repair damaged instruments.
- Take out of the packaging carefully

4. Technical data

Maximum output voltage of the generator U_{max}

$500V_p$, $300V_p$, $250V_p$ (depending on the model) with bipolar electrodes

500 V_p or. 300 V_p with bipolar forceps

500 V_p bipolar forceps Orbitaris

500 V_p bipolar forceps Classic

300 V_p bipolar scissors

250 V_p bzw. 300 V_p bipolar clamps

Suitable adapters / cables

Adapter:
There are two different adapters (see catalog):

- Adapter for European flat stretchers
- Adapter for US cables

Cables:
Connections (connection cable: Erbe / Storz 12.5mm Ø, Martin / Berchthold 8mm Ø Aesculap / Wolf, Valleylab / Lamidey / EMC and 2-pin U.S. Standard Eschmann are compatible with the Reda products

Pipes: Make sure that you only use compatible pipes from the REDA catalog!

Handles: Make sure that you only use compatible handles from the REDA catalog!

HF generators:

All of our items are compatible with: Erbe, Martin, Storz, Select, Olympus, Valleylab, Aesculap, Berchtold.

Storage and transport conditions

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

5. Proper use / indication

In high-frequency surgery (hereinafter referred to as HF surgery; also diathermy or electrocautery), high-frequency alternating current is passed through the human body in order to damage or cut tissue in a targeted manner. A major advantage over conventional cutting techniques with the scalpel is that the bleeding can be stopped at the same time as the incision is made by occluding the affected vessels. The devices used are also known as electric scalpel.

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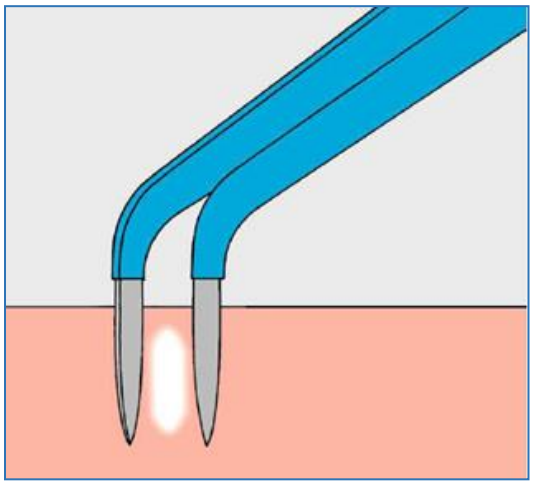
With the bipolar technique, in contrast to the monopolar technique, the current only flows through a small part of the body - that in which the surgical effect (incision or coagulation) is desired. Two mutually isolated electrodes, between which the HF voltage is applied, are led directly to the surgical site. The circuit is closed via the tissue in between. The thermal effect takes place in the tissue between the electrodes (in the picture the tips of the tweezers).
Compared to monopolar technology, 20–30% less power is required. The surrounding tissue is not damaged because there is no current flowing here and measuring devices on the patient (e.g. EKG) are not disturbed. This method is well suited for critical and precise applications such as microsurgery, neurosurgery and ENT surgery.
The bipolar HF instruments are used for coagulation when dissecting, grasping or cutting tissue in minimally invasive procedures. Depending on the area of application, different electrode attachments can be attached.

- Bipolar dissector
- Bipolar scissors
- Bipolar grasping forceps
- Bipolar forceps
- Bipolar forceps

6. Connection to the HF device in bipolar mode
First, the bipolar instrument is connected to the HF generator with a bipolar cable. The current paths in the patient's body are limited to one side of the instrument tip to the other.



Bipolar coagulation is the most commonly used technique. Bipolar forceps, which are available in a variety of different designs, are mostly used here.
Since the technology is mainly used in areas of difficult surgical interventions, it is of particular importance to keep the tweezer tips clean during the course of an operation. Tweezer tips on which a coagulate has adhered tend to an increased extent to an adhesive effect. This effect can result in an already caogulated vessel starting to bleed again after removing the tweezers.

The following conditions must be met:

- Prohibition of contact with protruding bones
- Prohibition of plant on scar tissue
- Prohibition of installation over implants
- Prevent moisture inclusions
- Before each use, the instrument must be examined for visible damage and wear, e.g. cracks, breaks or defects in the insulation
- Do not use any flammable or explosive substances
- No contact with drapes or other flammable materials
- Only coagulate if the contact surfaces are within sight and have good contact with the tissue to be coagulated.
- 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

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. Avoid touching the electrode with the trocar!

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7. Contraindications

When resecting malignant tumors, the electric knife should not be used close to the tumor, as the pathologist cannot assess the burned cut surfaces and cannot make a statement as to whether the tumor has been completely removed (in sano). However, there is nothing to prevent the resection surfaces from being covered with the cautery in order to destroy the tumor seed (of course not on the preparation side).

- 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

8. 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

9. Warnings / Precautions

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 does not occur despite the standard setting of the HF device, never increase the output power of the device without prior checking. In detail, the following must be checked: correct contact of all HF plugs and cables, functioning of the foot switch or the finger switch on the handle, insulation of the HF cables and the instrument as well as cleanliness of the distal end of the electrodes.
Before the start of the operation, a fault-free transmission (e.g. without noise) of the monitors must be checked. Endogenous burns are burns caused by high current density in the patient's tissue. The causes can include: The patient unintentionally comes into contact with electrically conductive parts. If HF cables come into direct contact with the skin, capacitive currents can cause burns.
In the event of deviations in the output power of the HF device, the operation must be interrupted immediately to avoid endangering the patient. Please note the error analysis in the operating instructions for your HF generator.

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Exogenous burns are burns from the heat of ignited liquids or gases. Explosions are also 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 generators, trocars / trocar sleeves and corresponding endoscopes.

10. 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.

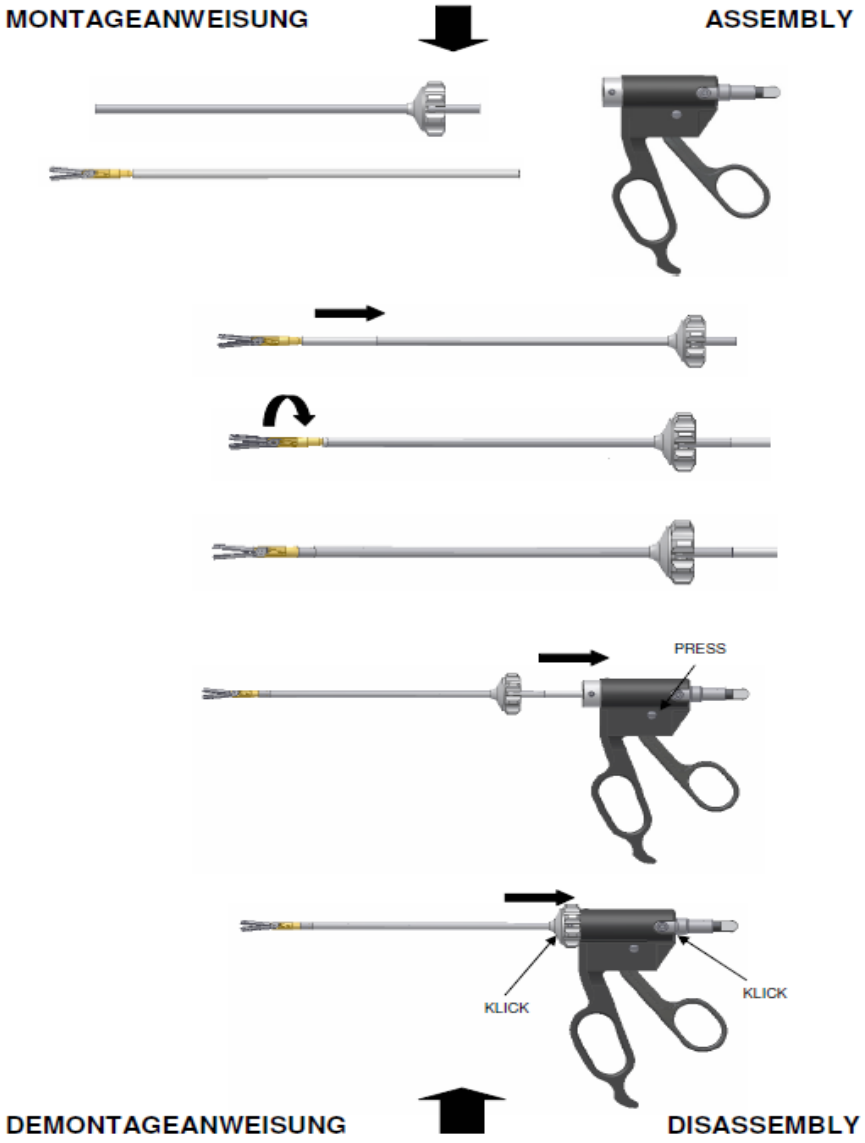
11. Use

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 should remain in the patient!

Please ensure that the instrument has been properly installed before use!

12. ⚠ Assembly



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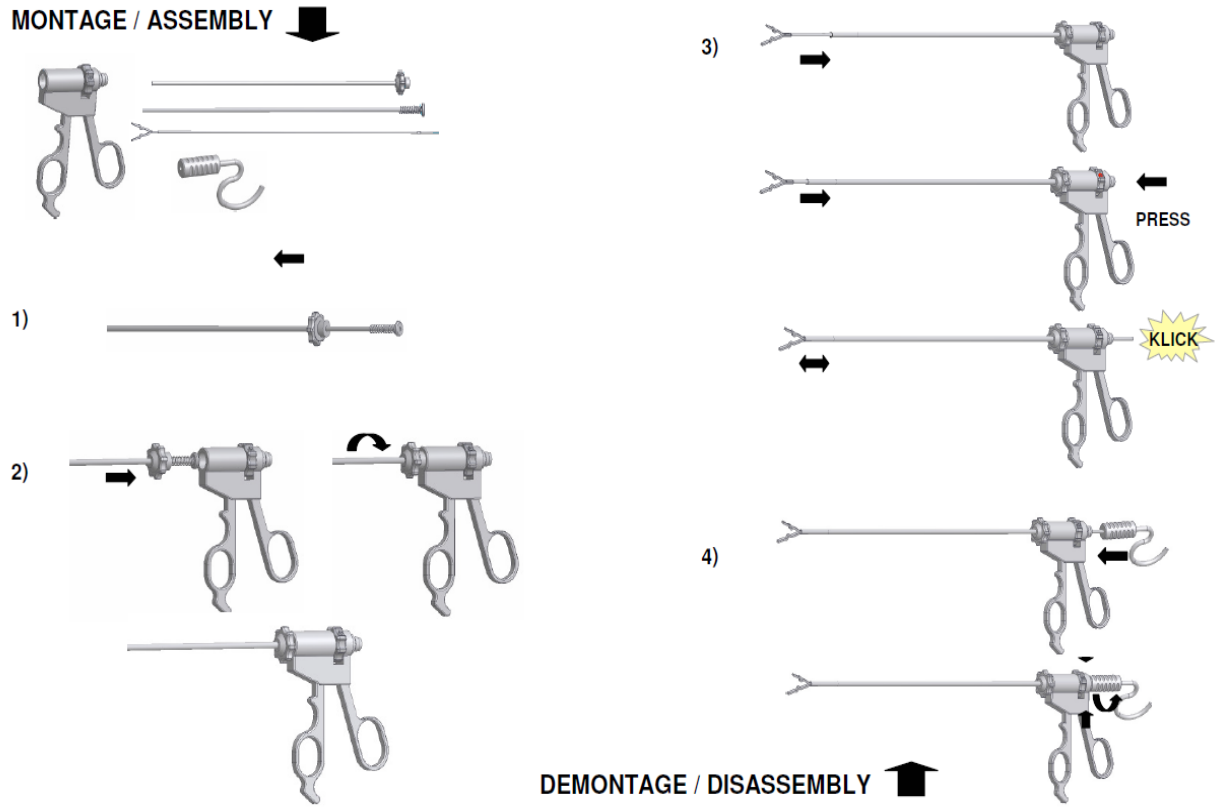

13. Proper installation

For proper installation, the following instructions must be followed:

1. Connect the power connection cable to the high-frequency power unit for electrosurgery.
2. Connect the trocar into the shaft as shown above (see assembly).
3. Connect the HF electrode to the shaft provided.
4. Turn the electrode to the right.
5. Then connect the shaft to the handle and slide it until it clicks into place.
6. Switch on the generator. As far as possible, avoid any direct contact between the HF connection cable and the patient.

14. Preparation and maintenance

The instrument must be cleaned of all blood and other residues with a pH-neutral cleaning agent for preliminary cleaning and 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.

Automated reconditioning

(Pre) cleaning: (also suitable in CSSD)
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). Temperature max. 93 ° C with a holding time of 10 minutes.

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. Trapped Remove 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. Clean the inserted instrument manually with a soft brush. Brush all surfaces several times.
4. The following applies only to ducts and inner pipe surfaces: move the brush in and out of the pipe at least six times. Rinse the pipes with deionized water. Repeat this procedure.
5. 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. Unless otherwise recommended by the disinfection manufacturer, disinfect for 7 ± 1 min at 80 ° ± 5 ° C. Rinse the instruments extremely thoroughly with demineralized water to completely remove the disinfectant.

Drying:
Manual drying takes place using a lint-free cloth and, in particular for drying cavities and channels, with sterile compressed air.

Cleaning agent: For recommendation, see information on validation of reprocessing.

Automated reprocessing is always preferable to manual reprocessing!

NON STERILE **Sterilization**
Sterilization of the products with the fractionated pre-vacuum process (according to ISO 13060 / ISO 17665) taking into account the respective national requirements.

- 3 pre-vacuum phases with at least 60 mbar pressure
- Heating to a sterilization temperature of 134 ° C
- Shortest holding time: 3 min.
- Drying time: at least 15 min.

Storage
Store the sterilized instruments in a dry, dust-free environment at moderate temperatures of 5 ° C to 40 ° C.

Information on reprocessing validation
The following test instructions, materials and machines were 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. 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.

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	-30°C bis +40°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 more or less 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

With the appropriate care and provided that they are undamaged and fully functional, the instruments can be reprocessed and reused. 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.

disposal

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

18. 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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