Instructions

ERAGON

Forceps and Scissors
monopolar, single assembly, 5 mm
Important general instructions for use

Ensure that this product is used only as intended and described in this instruction manual, by adequately trained and qualified personnel, and that maintenance and repair is only carried out by authorized specialized technicians.

Use this product only with the combinations and with the accessories and spare parts listed in this instruction manual. Use other combinations, accessories and replacement parts only if they are expressly intended for this use and if the performance and safety requirements are met.

Reprocess the products before every application and before returning them for repair as required by the instruction manual in order to protect the patient, user or third parties.

Subject to technical changes!

Due to continuous development of our products, illustrations and technical data may deviate slightly from the data in this manual.

CAUTION:

Federal law restricts this device to sale by or on the order of a physician.

Safety instructions and levels of danger

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Level of danger</th>
</tr>
</thead>
<tbody>
<tr>
<td>🚨</td>
<td><strong>WARNING!</strong> Failure to observe can result in death or serious injury.</td>
</tr>
<tr>
<td>🚨</td>
<td><strong>CAUTION!</strong> Failure to observe can result in slight injury or damage to the product.</td>
</tr>
<tr>
<td>🚫</td>
<td><strong>IMPORTANT!</strong> Failure to observe can result in damage to the product or surrounding.</td>
</tr>
<tr>
<td>📝</td>
<td><strong>NOTE!</strong> Tips for optimum use and other useful information.</td>
</tr>
</tbody>
</table>

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0 GA-S 025
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1 Intended use

The **ERAGON** Forceps and scissors are used for endoscopically controlled grasping, manipulation and cutting, as well as for the dissection of soft tissue parts and organs.

If suitable and adequately marked products are used in conjunction with this product, smaller hemorrhages can be coagulated by means of unipolar HF current.

**Holding, grasping and dissection forceps**
are used to hold, manipulate and dissect soft tissue parts or organs, suture material, needles etc.
These products offer thermal tissue treatment if marked accordingly.

**Biopsy and excision forceps, hook punches**
are used to transsect tissue or withdraw tissue for biopsies, as well as thermal tissue treatment if the products are marked accordingly.

**Scissors, hook scissors**
are used for cutting and transsecting tissue, as well as thermal tissue treatment if the products are marked accordingly.

These products are exclusively intended for use by medical staff and may only be used by medically qualified and adequately trained persons.

2 Indications and field of use

For examination, diagnosis and / or therapy with endoscopic accessories. These instruments are used in the medical disciplines of:
- Surgery
- Urology
- Thoracoscopy
- Gynecology

3 Contraindications

- **CJD** - Creutzfeldt Jakob Disease or
- **vCJD** - Variant of Creutzfeldt-Jakob Disease
- **BSE** - Bovine Spongiform Encephalopathy; so-called mad cow disease (e.g. Creutzfeldt-Jakob Disease)
- **TSE** - Transmissible Spongiform Encephalopathy

On the basis of the patient’s general condition the doctor in charge must decide whether the planned use is possible or not.
Follow the laws and regulations valid in your country.
For further notes and instructions please refer to the latest medical literature.
Contraindications directly related to the product are presently unknown.

4 Combinations

The **ERAGON** forceps and scissors are used in conjunction with endoscopes and endoscopic accessories (such as trocar sleeves).
In addition, the monopolar forceps and scissors are used in conjunction with monopolar HF devices and suitable HF cables.

⚠️ **CAUTION!**

*Do not combine products incorrectly!*

*Injuries of the patient, user or third parties as well as damage to the product are possible.*

*Different products should only be used in combination if their intended uses and relevant technical data (working length, diameter, peak voltage, etc.) are the same.*

*Follow the instruction manuals of the products used in combination with this product.*

*Follow the “Notes and instructions on HF applications”, order no.: GA-S 002 as well as the HF device manufacturer’s instructions.*
5.1 Legend and identification

<table>
<thead>
<tr>
<th>Item</th>
<th>Designation</th>
<th>Item</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Jaw section / scissors</td>
<td></td>
<td>Grip variants:</td>
</tr>
<tr>
<td>2</td>
<td>Sheath tube, insulated</td>
<td>a</td>
<td>With HF connector (unipolar) and lock</td>
</tr>
<tr>
<td>3</td>
<td>Luer locking cap with tab</td>
<td>B</td>
<td>With HF connector (unipolar) without lock</td>
</tr>
<tr>
<td>4</td>
<td>Luer connector</td>
<td>C</td>
<td>With lock without HF connector</td>
</tr>
<tr>
<td>5</td>
<td>Star wheel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>HF connector (unipolar)</td>
<td>#</td>
<td>Product no.</td>
</tr>
<tr>
<td>7</td>
<td>Movable grip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Lock</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Fixed grip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Locking lever</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Trigger</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Symbol | Designation

⚠️ Caution, consult ACCOMPANYING DOCUMENTS!

REF    | Order no.
LOT    | Lot designation
SN     | Serial no.

Identification in conformity with medical devices directive 93/42/EEC only valid if the product and/or packaging is marked with this symbol. Products of category Ila and above, as well as sterile products or products with measuring function of category I, are additionally marked with the code no. of the notified body (0124).
CAUTION!
The products have only limited strength!
Excessive force will cause damage, impair the function and therefore endanger the patient.
Due to the small dimensions required, the products have only limited strength. Use these products only to grasp and ablate small, soft tissue portions or organs.
Immediately before and after each use, check the products for damage, loose parts and completeness.
Make sure that no missing parts remain in the patient.
Do not use the products if they are damaged or incomplete or have loose parts.

6.1 Preparation

- Carry out a visual check: see sections 7 and 7.1
- Close the luer connector (4) with luer lock cap (3) (Fig. 1).

6.2 Handle with lock

6.2.1 Working with the lock (8)

- Turn the locking lever (10) from position I to position II (Fig. 4).
  - The lock (8) is activated.

Closing the forceps:
- The lock (8) engages automatically in the required position (Fig. 3).

Opening the forceps:
- Push the trigger (11) (Fig. 3).
  - The lock (8) disengages.
6.2.2 Working without the lock

- Turn the locking lever (10) from position II to I (Fig. 4).
- Carry out a function check: see section 7.2

6.3 Additional notes and instructions for use

Function of the star wheel (5):
The star wheel (5) serves to turn the grasped tissue portion or organ to a specific position (5) (Fig. 5).

![Fig. 5](image-url)

**NOTE!**
Increasing the pressure onto the movable grip (7) reduces the rotatability of the star wheel (5).

**IMPORTANT!**
Insert and retract the forceps and scissors only with closed jaws.
Follow the "Notes and instructions on HF applications", order no.: GA-S 002 as well as the HF device manufacturer’s instructions.

**CAUTION!**
When combined with HF surgical devices, the forceps and scissors with unipolar HF connector must only be used at a maximum recurring peak voltage of 2 kV and are only suitable for short coagulation times and for coagulating small hemorrhages.

Any use with forced coagulation or spray coagulation over 2 kV is not permissible!

**WARNING!**
Danger of injury if the monopolar forceps and scissors are not visible through the scope!

Inadvertent tissue damage as well as damage to the distal end of the endoscope and instrument parts are possible.

Use the monopolar forceps and scissors only within the given specifications (voltage endurance, mode of operation).

Activate the the monopolar forceps and scissors only when the live HF part is fully visible through the scope and touches the area to be treated.

- Apply the neutral electrode.
  - See "Notes and Instructions on HF Applications", order no. GA-S 002.
- Connect the HF connection cable (product no.: 8106.xxx) with the HF connector (6) and the HF surgical device (Fig. 6).

**NOTE!**
Encrusted and soiled jaws or cutting edges impair the HF performance during the intervention.

- Dissolve any encrustations or soiling on the coagulation surfaces with 3% hydrogen peroxide solution ($\text{H}_2\text{O}_2$-solution) and wipe off with a gauze pad.
  - Then rinse with sterile water.
7 Checks

CAUTION!
Be careful if products are damaged or incomplete!
Injuries of the patient, user or others are possible.
Run through the checks before and after each use.
Do not use the products if they are damaged, incomplete or have loose parts.
Return damaged products together with any loose parts for repair.
Do not attempt to do any repairs yourself.

7.1 Visual check

- Check the instruments, in particular the distal areas, as well as the accessories, for:
  - damage
  - sharp edges not suitable for the application
  - loose or missing parts
  - rough surfaces
- Check the luer lock cap (3) for damage and replace if necessary.
- Check the insulation of the HF cable for damage.
  - Replace the HF cable if the insulation is damaged.
- Check the insulation of the sheath tube (2) for mechanical damage and dielectric breakdown (punctures). (Fig. 7)
  - Do not use the forceps and scissors if the insulation is damaged.
- Any lettering, labeling or identification necessary for the safe intended use must be legible.
  - Missing or illegible lettering, labeling or identification leading to wrong handling and reprocessing must be reinstated.

CAUTION!
Damaged surface in the joint area of the forceps!
The joint pin may loosen.
Check for surface changes such as hair cracks etc. at the hinge pin.

7.2 Function check

- Check that the jaws open and close properly.
- Check that the jaw section (1) can be rotated with the star wheel (5).
8 Reprocessing and maintenance

⚠️ WARNING! Creutzfeldt Jakob Disease!

If the patient is suspected of having Creutzfeldt-Jakob Disease (CJD) or a variant of Creutzfeldt-Jakob Disease (vCJD) or the latter have been diagnosed, adequate measures must be taken to prevent possible transmission to other patients, users and third parties.

For this purpose, apply the country-specific reprocessing guidelines and regulations.

⚠️ IMPORTANT!

Further notes and instructions on reprocessing are described in manual GA-J020 “Reprocessing of RICHARD WOLF Heat-stable Instruments” and must be followed.

8.1 Disassembly before cleaning

- Remove the luer lock cap (3) (Fig. 9).

Figure 10 on the section on manual cleaning in the reprocessing instructions on page 8.
8.2 Reprocessing procedure

The table below describes the validated reprocessing method for Eragon forceps, scissors and punches.

**IMPORTANT!**
Due to the product design and the materials used it is not possible to define a specific limit of the maximum allowable reprocessing cycles. The life cycle of medical products is defined by their function and proper handling.

Before defective products are returned for repair, they must have gone through the entire reprocessing cycle.

The user must make sure that the reprocessing process including the resources, material and personnel are suited to reach the required reprocessing results.

The state of the art and national laws require that validated processes be followed.

**IMPORTANT!**
Further notes and instructions on reprocessing are described in manual GA-J020 "Reprocessing of RICHARD WOLF Heat-stable Instruments" and must be followed.

---

### Reprocessing guide:

<table>
<thead>
<tr>
<th>Preparation at the point of use:</th>
<th>Directly after use, remove any coarse soiling from the instruments. Immediately after use, rinse out hollow spaces with a 5 ml syringe filled with water. Do not use any fixing or setting agents or hot water (&gt;40°C) as this will bake the residues to the surfaces and may have a negative impact on cleaning.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transport:</td>
<td>Safe storage and transport of the instruments to the reprocessing room in a closed container to prevent damage to the instruments and contamination of the environment.</td>
</tr>
<tr>
<td>Precleaning:</td>
<td>Before cleaning, remove the luer lock cap (3) (see section 8.1). Rinse out instruments for 20 seconds or, in pulsed mode, with 5 pressure surges (3 - 4 bar) using a water cleaning gun.</td>
</tr>
</tbody>
</table>
| Cleaning: Manual cleaning        | 1. Immerse instruments in a cleaning solution for at least 5 minutes.  
  2. Clean instruments with a soft brush until all visible contaminants are removed.  
  3. Rinse out instruments for 20 seconds or, in pulsed mode, with 5 pressure surges (3 - 4 bar) using a water cleaning gun.  
  * Clean the jaw section of the instrument and hinge area using a brush. |
| Cleaning: Machine cleaning        | 1. Immerse instruments in a cleaning solution for at least 5 minutes.  
  2. Clean instruments with a soft brush until all visible contaminants are removed.  
  3. Rinse out instruments for 20 seconds or, in pulsed mode, with 5 pressure surges (3 - 4 bar) using a water cleaning gun.  
  * Clean the jaw section of the instrument and hinge area using a brush. |
| Disinfection:                    | 1. Immerse instruments in an approved disinfectant solution, for exposure time refer to the manufacturer’s instructions.  
  2. Then rinse the instruments thoroughly with fully demineralized water for at least 15 seconds using a cleaning gun.                                                                 |
| Drying:                          | Manual drying:  
  Dry outside of instruments using a sterile lint-free disposable cloth or swab, dry any hollow spaces with filtered compressed air.                                                                                                       |
| Drying:                          | Drying of instruments using the washer / disinfector drying cycle. If necessary, additional manual drying can be achieved using a sterile lint-free disposable cloth or swab. Dry hollow spaces with filtered compressed air. |
| Care:                            | After manual / machine disinfection, if required:  
  Sparingly oil the joint of the jaw section (1) with 1 drop of instrument oil. - All other surfaces must be oil-free!  
  Remove any excess oil.                                                                                                     |
| Function check, maintenance:     | Check visually for cleanliness. If necessary, repeat the reprocessing procedure until the instrument appears visually clean.                                                                                                                           |

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**Reprocessing guide:**

**Preparation at the point of use:**

Directly after use, remove any coarse soiling from the instruments. Immediately after use, rinse out hollow spaces with a 5 ml syringe filled with water. Do not use any fixing or setting agents or hot water (>40°C) as this will bake the residues to the surfaces and may have a negative impact on cleaning.

**Transport:**

Safe storage and transport of the instruments to the reprocessing room in a closed container to prevent damage to the instruments and contamination of the environment.

**Precleaning:**

Before cleaning, remove the luer lock cap (3) (see section 8.1). Rinse out instruments for 20 seconds or, in pulsed mode, with 5 pressure surges (3 - 4 bar) using a water cleaning gun.

**Cleaning:**

**Manual cleaning**

1. Immerse instruments in a cleaning solution for at least 5 minutes.  
2. Clean instruments with a soft brush until all visible contaminants are removed.  
3. Rinse out instruments for 20 seconds or, in pulsed mode, with 5 pressure surges (3 - 4 bar) using a water cleaning gun.  
   * Clean the jaw section of the instrument and hinge area using a brush.

**Machine cleaning**

Pre-clean the instruments manually before automatic machine cleaning.  
Place the instruments in open condition onto the inserts of the MIC rack cart.  
Vario-TD program (without disinfection cycle)  
   * 4 min of pre-cleaning using cold water.  
   * Empty  
   * 5 min of washing at 55°C using cleaning agent  
   * Empty  
   * 3 min of neutralization with warm tap water (>40°C)  
   * Empty  
   * 2 min of intermediate rinsing with warm tap water (>40°C)  
   * Empty

**Disinfection:**

1. Immerse instruments in an approved disinfectant solution, for exposure time refer to the manufacturer’s instructions.  
2. Then rinse the instruments thoroughly with fully demineralized water for at least 15 seconds using a cleaning gun.

**Drying:**

**Manual drying:**

Dry outside of instruments using a sterile lint-free disposable cloth or swab, dry any hollow spaces with filtered compressed air.

**Drying of instruments using the washer / disinfector drying cycle:**

If necessary, additional manual drying can be achieved using a sterile lint-free disposable cloth or swab. Dry hollow spaces with filtered compressed air.

**Care:**

After manual / machine disinfection, if required:  
Sparingly oil the joint of the jaw section (1) with 1 drop of instrument oil. - All other surfaces must be oil-free!  
Remove any excess oil.

**Function check, maintenance:**

Check visually for cleanliness. If necessary, repeat the reprocessing procedure until the instrument appears visually clean.

Carrying out a visual check: see section 7.1
| **Assembly before sterilization** | Do not close the luer connector (4) with the luer lock cap (3) until **just before** use. |
| **Sterilization:** | Steam sterilization at 132°C (270°F) using Pre-vacuum steam sterilization with an exposure time of 4 minutes and a dry time of 20 minutes. |
| **Additional instructions:** | It is the user’s responsibility to ensure that the reprocessing equipment has been installed, calibrated and validated according to manufacturer specifications. |
9 Technical data and order data
See flyer BB-S 025 “Overview of technical data and order data”

10 Spare parts and accessories

<table>
<thead>
<tr>
<th>Illustration</th>
<th>Product no.</th>
<th>Designation, technical data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>88702</td>
<td>Luer lock cap</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Packaging unit: 10/pkg</td>
</tr>
<tr>
<td></td>
<td>8106.032</td>
<td>HF Monopolar Connection Cable, 3 m (ERBE / ACC / ICC / VIO)</td>
</tr>
<tr>
<td></td>
<td>8106.052</td>
<td>HF Monopolar Connection Cable, 5 m (ERBE / ACC / ICC / VIO)</td>
</tr>
<tr>
<td></td>
<td>8106.132</td>
<td>HF Monopolar Connection Cable, 3 m (ERBE T series)</td>
</tr>
<tr>
<td></td>
<td>8106.152</td>
<td>HF Monopolar Connection Cable, 5 m (ERBE T series)</td>
</tr>
<tr>
<td></td>
<td>8106.031</td>
<td>HF Monopolar Connection Cable, 3 m (Martin / Berchtold / Aesculap)</td>
</tr>
<tr>
<td></td>
<td>8106.051</td>
<td>HF Monopolar Connection Cable, 5 m (Martin / Berchtold / Aesculap)</td>
</tr>
<tr>
<td></td>
<td>8106.033</td>
<td>HF Monopolar Connection Cable, 3 m (Bovie / Valleylab / Erbe Int.)</td>
</tr>
<tr>
<td></td>
<td>8106.053</td>
<td>HF Monopolar Connection Cable, 5 m (Bovie / Valleylab / Erbe Int.)</td>
</tr>
<tr>
<td></td>
<td>8106.034</td>
<td>HF Monopolar Connection Cable, 3 m (Eschmann and other devices with 4 connectors)</td>
</tr>
<tr>
<td></td>
<td>8106.054</td>
<td>HF Monopolar Connection Cable, 5 m (Eschmann and other devices with 4 connectors)</td>
</tr>
</tbody>
</table>

The products can be combined as required provided the relevant technical data and intended uses are observed. For the total overview please refer to the latest catalog sheets and brochures or contact Richard Wolf or your representative.

11 Operating, storage, transport and shipping conditions

| Operating conditions | +10°C to +40°C, 30% to 75% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa |
| Storage, transport and shipping conditions | -20°C to +60°C, 10% to 90% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa |

**NOTE!**
To prevent damage during transport or shipment of the products we recommend using the original packaging material.

11.1 Disposal of product, packaging material and accessories
For the disposal comply with the country-specific laws and regulations.

For further information please contact the manufacturer.
Warranty and Customer Service

Richard Wolf guarantees our instruments to be free from any defects in materials and workmanship under normal use and service for one year. Richard Wolf general terms and conditions may be found on the back of our invoice.

Parts delivered separately by Richard Wolf are subject to all of the same general terms and conditions for our products, including the limitations of warranty and liability.

All products should be returned to Richard Wolf for any necessary or desired repair or part replacement. No product repair or part replacement should be done other than by Richard Wolf unless the care and instruction manual or other written information indicates that repair or part replacement is authorized. If authorized, parts must be replaced only by parts supplied or specified by Richard Wolf, and product repair and part replacement must be done in strict conformance with Richard Wolf specifications and instructions for repair and part replacement, including post replacement testing and recalibration. Failure to follow this requirement in any way can be dangerous to you, your personnel and your patients and voids the warranty for the product repaired or the product in which the part was replaced and if the part was supplied by Richard Wolf, for that part.

Delivery by Richard Wolf of technical documents such as circuit or other design diagrams does not constitute authorization for product repair or part replacement. Richard Wolf instruments and other products should never be modified or altered under any circumstances.

Contact Richard Wolf if you have any question (1) whether replacement of a part or a repair is authorized by Richard Wolf, or (2) whether you have complete instructions and specifications for part replacement or repair.

These instructions do not attempt to cover all details or variations in equipment, nor to provide for every possible contingency to be met in connection with installation, operation, or maintenance. Should further information be required or should problems arise which are not covered sufficiently for the purchaser’s purpose, the matter should be referred to Richard Wolf Medical Instruments Corporation.

Our national sales and service offices, as well as our manufacturing facility, are located in Illinois. Trained manufacturer’s representatives are located throughout the U.S. to serve you. For any questions regarding these instruments, or to place an order, contact Richard Wolf customer service department at 847-913-1113 or 800-323-WOLF (9653).

INSTRUMENT ORDERING POLICY
Richard Wolf reserves the right to make substitutions, if necessary, without prior notice.

REPAIR POLICY
Defective merchandise will be repaired or replaced at no charge to the customer, provided the customer delivers such defective merchandise prepaid. Any repairs, maintenance or servicing of Richard Wolf merchandise by anyone other than a factory authorized representative will render our warranty null and void.

REPAIR SHIPMENTS
When returning your instrument for repair, we suggest that you prevent shipping damage to the instrument by reusing the box that it was originally shipped in. Richard Wolf also recommends that the instrument be insured for an amount to cover the cost of replacement.

IMPORTANT
For general safety and health reasons, Richard Wolf requires that you clean and sterilize all instruments before returning them for repair. If instruments are received in an unsanitary condition, Richard Wolf will clean and sterilize each instrument and add a $100.00 cleaning charge for each instrument requiring cleaning.