Instruction for use
Key

Sterile blade

Blade
Blade rod
Blade holder
Grip area
Push rod
Teeth
Spring latch
Jaw
Electrodes
Mounting marking
Slotted ring for blade rod latching
Key

Handle

Rotation wheel
Mounting marking
Pushbuttons
Blade trigger
Locking knob
Jaw holder
Jaw actuation lever

Cable with handswitch

Connector for BOWA ARC generator
Handswitch
Cleaning adapter

Cleaning adapter for jaw / handle

Cleaning adapter for push rod

Cleaning brush

Reprocessing basket & lid
Contents

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1 Using this operating manual

This operating manual is part of the product. BOWA-electronic GmbH & Co. KG assumes no liability and provides no warranty whatsoever for any damage or consequential damage arising from non-compliance with this operating manual.

- Read the operating manual, in particular the safety instructions (see section 3, page 10) carefully and thoroughly before use.
- Store the operating manual in a safe place throughout the service life of the device.
- Keep the operating manual accessible to operating theatre personnel.
- Give the operating manual to each successive owner and/or user of this device.
- Always update the operating manual whenever you receive additional information from the manufacturer.

1.1 Scope of validity

This operating manual applies only to the parts of the instrument ERGO 315R listed below.

<table>
<thead>
<tr>
<th>REF</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>770-510</td>
<td>ERGO 315R Handle</td>
</tr>
<tr>
<td>770-522</td>
<td>ERGO 315R Jaw 275 mm</td>
</tr>
<tr>
<td>770-523</td>
<td>ERGO 315R Jaw 360 mm</td>
</tr>
<tr>
<td>770-532</td>
<td>ERGO 315R Push rod 275 mm</td>
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<td>ERGO 315R Push rod 360 mm</td>
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<td>ERGO 315R Blade rod 360 mm</td>
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<tr>
<td>770-998</td>
<td>ERGO 315R Blade sterile (10 Pcs.)</td>
</tr>
<tr>
<td>358-245</td>
<td>ERGO 315R Cable with handswitch</td>
</tr>
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<td>723-050</td>
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</tr>
<tr>
<td>773-982</td>
<td>ERGO 315R Reprocessing basket</td>
</tr>
<tr>
<td>773-983</td>
<td>ERGO 315R Lid for basket</td>
</tr>
<tr>
<td>723-000</td>
<td>Cleaning brush set</td>
</tr>
</tbody>
</table>
1.2 Symbols and notation

Structure of warning instructions

**SIGNAL WORD**
Type, source and consequences of the hazard
▶ Measure for avoiding the hazard.

Hazard levels of warning instructions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Hazard level</th>
<th>Probably of occurrence</th>
<th>Consequences of non-compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="DANGER" /></td>
<td>DANGER</td>
<td>Immediate risk</td>
<td>Death or serious injuries</td>
</tr>
<tr>
<td><img src="image" alt="WARNING" /></td>
<td>WARNING</td>
<td>Possible risk</td>
<td>Death or serious injuries</td>
</tr>
<tr>
<td><img src="image" alt="CAUTION" /></td>
<td>CAUTION</td>
<td>Possible risk</td>
<td>Minor injuries</td>
</tr>
<tr>
<td><img src="image" alt="NOTE" /></td>
<td>NOTE</td>
<td>Possible risk</td>
<td>Property damage</td>
</tr>
</tbody>
</table>

Tips

![Tips](image)
Tips to make your work easier or supplementary explanatory information for a procedure.

Other symbols and notation

<table>
<thead>
<tr>
<th>Symbol or notation</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓</td>
<td>Prerequisite for an activity</td>
</tr>
<tr>
<td>▶</td>
<td>Activity with one step</td>
</tr>
<tr>
<td>1. 2.</td>
<td>Activity with several steps in strict sequence</td>
</tr>
<tr>
<td>‥</td>
<td>Result of preceding activity</td>
</tr>
<tr>
<td>•</td>
<td>List (first level)</td>
</tr>
<tr>
<td>‥</td>
<td>List (second level)</td>
</tr>
<tr>
<td><strong>Emphasis</strong></td>
<td>Emphasis</td>
</tr>
<tr>
<td>..., see section xxx, page xxx</td>
<td>Cross-reference</td>
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</table>
2 Intended use

2.1 Indications

The ERGO 315R instrument is intended to be used to seal arterial and venous blood vessels and vascular tissue structures in laparoscopic and open surgical procedures in varied surgical disciplines (including but not limited to general surgery, gynecology, urology, thoracic surgery and other).

The instrument can also be used to cut tissue.

The ERGO 315R instrument is intended to be used with the bipolar vessel sealing operating mode of BOWA ARC generators.

2.2 Contraindications

Do not use vessel sealing instruments if, in the opinion of an experienced physician or according to current professional literature, such use would cause endangerment of the patient due, for example, to the general condition of the patient, or if other contra-indications are present.

---

**WARNING**

**Risk of patient injury**

- Do not use with vessels larger than 7.0 mm in diameter.
- The reliability of sealing must be assessed by the attending physician according to the nature of the vascularised tissue and the vessel pathology (arteriosclerosis, aneurysms, vascularisation, etc.).
- Do not use on the heart, on the central circulatory system or on the central nervous system.
- Do not use for contraceptive coagulation of the Fallopian tubes.
- Do not use vessel sealing for tissue groups with unknown content.
- Proceed cautiously when performing sealing in the vicinity of sensitive structures, such as nerves or ureter.
- Avoid grasping too much tissue for sealing – the jaws should not be full.
3 Safety

It is not necessary to use a neutral electrode with bipolar ligation instruments.

The instrument may only be used by trained medical staff. The surgeon and the medical technicians must be trained in and familiar with the fundamentals, codes of practice, and risks of HF surgery.

- Read the operating manual carefully and thoroughly before using the device.
- All serious incidents occurring in connection with the product must be reported to the manufacturer and to the competent authority of the country in which the user is established.

3.1 HF device

Observe the operating instructions of the HF device and the general instructions for electrosurgical operations.

The "BF" / "CF" application part of the HF device used is extended by the instrument connected to it.

3.2 HF cable

Improper use of HF cables can lead to patient injuries:

- When plugging or unplugging the HF cable, always grasp the connector directly.

The HF cable may cause interference to imagery on monitors.

- Never route the HF cable alongside a camera cable.
- Do not lay the HF cable in loops.
- Consult the operating manuals of the BOWA HF generators for additional information on interference with other devices.

3.3 Replaceable blade in blade holder

Do not recondition the replaceable blade and blade holder.

- Discard and replace used blades and blade holders.

3.4 Repair and service

Do not repair or service defective devices.

- Discard or replace defective devices.
3.5 Patients with pacemakers

Malfunction or destruction of the pacemaker can endanger the life of the patient or result in irreversible injuries to the patient.

---

**DANGER**

**Risk of patient injury**

- Never perform ambulant operations on patients with pacemakers.
- In cases of patients with pacemakers, consult the cardiologist before carrying out HF surgery.
- Set the demand pacemaker to a fixed frequency.
- Ensure that the pacemaker does not come into contact with the HF electrode.
- Keep a fully operational defibrillator within reach.
- Carry out a postoperative pacemaker check.

---

3.6 EMC instructions

Medical electrical devices are subject to special precautionary measures with regard to EMC. Observe the following instructions:

- The BOWA accessory is only intended to be connected to BOWA specified HF devices.
- Using the accessory with medical devices from other manufacturers can result in higher emission levels or reduced interference immunity.

---

**NOTE**

With combinations of medical devices, safety can only be assured if:

- the desired combination is allowed by the relevant operating manuals
- using the devices in the desired combination complies with the intended use and the interface specification.

Strict attention must be given to the operating manuals and interface specifications of medical devices used in combination.
4 Mode of operation

In bipolar HF surgery, tissue coagulation is achieved by applying a high-frequency AC current, which generates heat.

The ERGO 315R vessel sealing instruments are invasive surgical instruments for use in laparoscopic or open surgery. They are used through surgically produced access openings in conjunction with devices for endoscopic use, such as trocars and optics.

The active electrodes are the non-insulated areas of the jaws. The HF current flows from one electrode of the instrument through the biological tissue to the other electrode to produce the desired localized tissue effect.

With this method, sealing of a vessel or tissue segment carrying blood is achieved by HF current in combination with supplementary pressure. The sealed location is haemostatically tight with respect to systolic blood pressure and permanently closed.

The instrument can be used for vessels with diameters up to 7 mm.

The integrated cutting function of the ERGO 315R allows the tissue to be cut under treatment immediately after sealing without first changing instruments.

The electrodes can be opened, closed and latched by actuating the handle. A ratchet mechanism in the handle generates a reproducible mechanical pressure on the electrode tips when the handle is closed. The jaw can be rotated and positioned by a rotation wheel on the handle.
5 Assembly

5.1 Mounting the blade with the blade holder

CAUTION
Risk of injury from sharp blade

To avoid punctures and lacerations, always use the blade holder or a suitable aid for blade assembly.

☑ The blade and blade holder are supplied sterilized.

1. Remove the blade and blade holder from the sterile package.

2. To mount the blade, grasp the blade holder in the grip area. Position the blade rod on the blade holder as indicated by the markings on the blade holder and slide the blade rod in the direction indicated by the arrow until the blade clicks into place.
3. Lift the blade rod with the mounted blade slightly and pull it out of the blade holder. Discard the blade holder. Avoid bending the blade in the process.

4. Visually check the blade for correct assembly.
5.2 Assembling the vessel sealing instrument

Assemble the vessel sealing instrument in the sequence shown below.

1. [Part 1]
2. [Part 2]
3. [Part 3]
4. [Part 4]
**Insert the blade rod into the push rod**

- Insert the blade rod with the assembled blade into the push rod.

- Align the spring latch of the blade rod with the slotted ring of the push rod and insert the blade rod until it clicks in place.
Insert the push rod into the jaw

- Insert the push rod with the assembled blade rod into the completely opened jaw.

- Align the teeth of the push rod with the orange marking on the jaw.
Mount the jaw on the handle

- Assemble the jaw and handle.

1. Close the jaws with your fingers and guide the jaw into the handle until it latches with a click. Ensure that the orange marking on the handle is aligned with the marking on the jaw.
2. Continue holding the jaws closed with your fingers and slide the lever of the handle forward until it also latches with a click.

3. Check the vessel sealing instrument for proper opening, gripping and latching by actuating the handle.

4. Check the blade for ease of motion by actuating the blade trigger.

5. Unlatch the jaws by again actuating the handle.

6. Check whether the rotation wheel can be turned when the handle is unlocked.
Attach the cable with the handswitch

1. Attach the connection cable by inserting the handswitch in the handle.
2. Clamp the cable in the guide groove of the handle.

The handswitch can be operated from either side, making it suitable for both left-handed and right-handed use.
6 Operation

6.1 Before use

- The vessel sealing instrument is assembled (see section 5, page 13) and cleaned (see section 8, page 29).

**WARNING**

**Risk of patient injury due to incorrect device settings**

- Use only approved BOWA ARC generators with vessel sealing capability (see section 11, page 42).
- Select the settings of the HF generator according to the requirements of the procedure.

**Risk of patient injury**

- Use only suitable devices and accessories as described in the legend.
- Use only intact and sterilized devices.

**Risk of patient injuries from the combustion or explosion**

- Avoid contact with flammable gases and liquids, such as skin cleansers, disinfectants and anaesthetic gases.
- Avoid direct skin contact with HF cables.
- Skin-to-skin contact (e.g. between the patient's arms and body) should be avoided, e.g. by inserting dry gauze.

1. Switch on the HF device and connect the HF cable to the HF device.
2. Set the required settings on the HF device.
3. Perform a thorough visual inspection and functional test each time before using the vessel sealing instrument (see section 6.2, page 21 and section 8.6, page 37).

6.2 Function test in the OR

1. Check whether the electrodes can be easily opened and closed with the handle.
2. Lock the handle by pressing the operating lever.
3. Actuate the knife trigger and check it for ease of movement.
4. Check the activation by pressing the handswitch.
The activation signal sounds during activation of the handswitch.

### 6.3 During the operation

**WARNING**

**Risk of patient injury due to tissue clamping, especially with limited visibility**

- Prepare the tissue to be sealed so it is as free as possible in order to avoid unintentional clamping.
- Only carry out the operation with adequate visibility.

**Risk of patient injury due to hot electrode surfaces and steam emission**

- Instrument tips may still be hot immediately after HF power has been switched off.
- Maintain sufficient distance between instrument tips and sensitive tissue structures, such as nerves, pancreas or intestines.
- Ensure that hot vessel sealing instruments are not used for preparation.
- Do not lay the vessel sealing instrument on the patient.

**Introduce the instrument**

1. Using the handle, close the electrodes.
2. Insert the instrument into the trocar sleeve.

**Grasping, clamping and sealing tissue**

**WARNING**

**Risk of patient injury due to inadvertent activation of the vessel sealing instrument**

- Never use the Autostart function.
- Do not switch on the HF current before the active electrodes are in contact with the tissue to be coagulated and the handle is latched.
- Accidental activation of the vessel sealing instrument may cause injury to the patient.
3. Position the electrodes at the operation site.
4. Turn the rotation wheel (with open electrodes) to adjust the angle of the jaw.
5. Position the tissue to be sealed between the electrodes.
6. Close the electrodes to grasp the tissue. Never grasp too much tissue.
   ☑️ The tissue is grasped.
7. Latch the handle.
   ☑️ The tissue is clamped.
8. Using the handswitch of the instrument or the foot switch of the HF device, activate the HF current for coagulation:
   - A continuous acoustic signal sounds during the entire sealing process to indicate that power is being supplied.
   - An alternating acoustic signal indicates the end of the sealing process.

**WARNING**

**Incomplete sealing**

Avoid contact with metallic objects (clips, stents, etc.) in the area of the active electrode surfaces. They can affect energy output and lead to undesired effects.

9. Release the actuated switch.
10. Press the handle all the way to release the ratchet and open the electrodes.
    ☑️ The tissue is coagulated.

**Tissue separation**

☑️ The tissue has been grasped by the jaws and is coagulated.
WARNING
Strong bleeding may occur if the grasped tissue is cut before coagulation or vessel sealing

► With vessels, make several seals to the left and right of the cutting site as necessary.
► Before cutting, ensure that the tissue has been reliably sealed.
► Cut only in the sealed area.

11. To cut, pull the trigger and then release it.

⚠️ The tissue will be cut through the middle of the sealed area.

6.4 Withdrawal

WARNING
Risk of patient injury due to damaged or broken-off parts

► Check the vessel sealing instrument after each use. All parts must be present.

1. Close the electrodes.
2. Withdraw the vessel sealing instrument from the trocar sleeve.

6.5 After use

WARNING
Defective, worn and dirty electrodes may lead to functional failure of the vessel sealing instrument

► Clean the electrodes regularly with a moist cloth.
► Replace the jaw if the electrodes are damaged.
► Replace the blade after every operation.

► Prepare the vessel sealing instrument after use (see section 8, page 29).
7 Dismantling

7.1 Dismantling the vessel sealing instrument

WARNING
Risk of burns from hot electrode surfaces
▶ Do not touch the electrode surfaces immediately after use.

Risk of burns from current-carrying parts
▶ Disconnect the cable from the HF generator before dismantling.

▶ Disassemble the instrument in the reverse order of assembly (see section 5, page 13).
7.2 Disassembly

Dismantle the handswitch

▲ Press the connection cable handswitch out of the rear of the handle.

Dismantle the handle and jaw

1. Unlock the handle.
2. Press the locking knob on the back of the handle to open the jaw.
3. Then press the two push buttons on the rotation wheel simultaneously and pull the handle off the jaw.

Dismantle the jaw and push rod

- With the electrodes fully open, pull the push rod out of the jaw.
Dismantle the push rod and blade rod

- Press the spring latch of the blade rod and pull the blade rod out of the push rod.

7.3 Remove the blade

CAUTION
Risk of injury from sharp blade
- Be careful with the blade during dismantling.
- To avoid punctures and lacerations, always use a suitable aid for blade disassembly.

Risk of blade breakage due to incorrect dismantling
- Carefully pull the blade free to avoid breaking the blade.

- Use a suitable aid (needle holder, clamp, forceps, etc.) to remove the blade in the same way as a scalpel blade.
8 Cleaning

WARNING
Risk of patient injury from non-sterile vessel sealing instruments

➤ The vessel sealing instrument is not sterile when delivered. Clean and sterilize the instrument before use.
➤ Clean and sterilize the vessel sealing instrument before each subsequent use.
➤ Use only cleaning, disinfection and sterilization methods that have been validated for the specific devices and products concerned.
➤ Comply with the validated parameters for each cycle.
➤ Observe the applicable legal regulations in your country and the hygiene regulations of the hospital.

Vessel sealing instruments must always be cleaned, disinfected and sterilized before use. Effective cleaning and disinfection are essential for effective subsequent sterilization of the vessel sealing instruments.

1. Ensure that only adequately validated device- and product-specific methods are used for cleaning, disinfection and sterilization and that the validated parameters are complied with in each cycle.

2. Observe the applicable national legal regulations and the hygiene regulations of the hospital or clinic.

BOWA-electronic GmbH & Co. KG assumes no warranty for malfunction of the vessel sealing instruments in connection with disinfectants or the method used, including the effectiveness of the disinfectant.
The following information on the allowed number of preparation cycles should be regarded as a guideline. The actual number may vary depending on the stress level.

The number of reprocessing cycles of the individual instrument parts:
- Handle: up to 20 times
- Cable: up to 20 times
- Jaw: up to 20 times
- Push rod: up to 20 times
- Blade rod: up to 20 times

Preparation of the vessel sealing instrument comprises the following steps:
- Dismantling
- Soaking
- Manual removal of contamination
- Pretreatment in an ultrasonic bath
- Mechanical preparation in a cleaning and disinfection machine (CDM)
- Inspection
- Packing
- Autoclaving
- Storage

8.1 Dismantling

► Dismantle the vessel sealing instrument (see section 7, page 25)
► Remove the blade from the vessel sealing instrument and discard it (see section 7.3, page 28)

8.2 Soaking

► If necessary, first use a non-woven cloth or plastic brush to remove residual dirt.
► Soak the vessel sealing instrument immediately after use, not more than 2 hours after use.
To soak the distal jaw part, BOWA recommends a small tube filled with liquid, e.g. the Leonardo-Wet-Set® from Interlock Medizintechnik GmbH, which you push over the branches of the jaw part immediately after use.

Use only aldehyde-free disinfectants (e.g. with DGHM or FDA approval or CE mark).

The disinfectant used for soaking is intended solely for personal protection and does not replace subsequent disinfection.

### 8.3 Manual removal of contamination

**CAUTION**

Risk of infection due to water spray and vapours from the ultrasonic bath or with manual precleaning

- Wear a face mask and protective clothing.
- Adequate ventilation is recommended.

**NOTE**

Risk of material damage to the jaw by scouring products and metal brushes

- Never use scouring products or metallic brushes to clean the vessel sealing instrument.

**Recommended procedure**

1. **Rinse** all parts inside and outside after soaking, using a suitable spray gun.
2. **Clean** all parts inside and outside, using the included accessory brushes or other suitable plastic brushes.

3. **Rinse** all parts inside and outside after brushing, using a suitable spray gun.

**Handle**

- Clean the outside of the handle after soaking, using a suitable plastic brush.

**Jaw**

1. Rinse the jaw inside and outside after soaking, using a suitable spray gun.

2. Clean the outside of the jaw using a suitable plastic brush.

3. Clean the jaw inside using the included accessory brush or other suitable plastic brush.

4. Rinse the jaw inside and outside after brushing, using a suitable spray gun.

**Push rod**

1. Rinse the push rod inside and outside after soaking, using a suitable spray gun.

2. Clean the push rod outside using a suitable plastic brush.

3. Clean the push rod inside using the included accessory brush or other suitable plastic brush.

4. Rinse the push rod inside and outside after brushing, using a suitable spray gun.

**Blade rod**

- Clean the outside of the blade rod after soaking, using a suitable plastic brush.

### 8.4 Pretreatment in an ultrasonic bath

1. Place all parts of the vessel sealing instrument in the ultrasonic bath for at least 5 minutes. Position instrument parts with large surface areas in the ultrasonic bath such that they will not be damaged by the ultrasonic energy.

2. Use suitable cleaning and disinfection products for ultrasonic cleaning (see section 8.9, page 40).

3. Follow the manufacturer’s instructions with regard to the concentration and exposure time of the cleaning and disinfection products.
8.5 Automatic preparation in a CDM

NOTE
Cleaning adapter & reprocessing basket

BOWA has validated the automatic reprocessing using the cleaning adapters in the reprocessing basket. (optionally available)

8.5.1 Preparation for automatic cleaning – cleaning adapter

Mounting the cleaning adapter on the jaw
Mounting the cleaning adapter on the handle

Mounting the cleaning adapter on the push rod
8.5.2 Placing the parts in the cleaning and reprocessing basket

**NOTE**

Risk of damage to the instrument components from incorrect placement in the CDM

- Use the cleaning and reprocessing basket for cleaning to avoid damage to the instrument components.
- Ensure that the HF cable is not kinked or pinched.

Risk of damage to the instrument components when putting them in the cleaning and reprocessing basket or removing them from the reprocessing basket

- To avoid bending of the instrument components, ensure that they are clipped into the holders. Press the instrument components into the holders with equal pressure on both ends.

1. Connect the cleaning hoses of the CDM to the Luer Lock couplings of the cleaning adapters.
2. Place the instrument components with the attached cleaning adapters in the corresponding recesses in the cleaning and reprocessing basket as indicated by the symbols.
3. Feed the hoses out of the reprocessing basket through the openings in the end of the reprocessing basket provided for that purpose.
Ensure that:

- The instrument components are positioned to ensure exposure to the cleaning media
- The handle is cleaned in the unlatched position
- The HV cable is positioned separately in the reprocessing basket
- Close the reprocessing basket with the corresponding cover (optional accessory)

**Suitable cleaning and disinfection methods**

- Use a cleaning and disinfection machine (CDM) to clean and disinfect the vessel sealing instruments.

Manual methods are not recommended due to their significantly lower effectiveness.

- Ensure that the selected CDM fulfils the following requirements:
  - Verified effectiveness (e.g. DGHM or FDA approval or a CE mark in accordance with EN ISO 15883)
  - A verified program for thermal disinfection (at least 5 minutes at 90°C or an A0 factor greater than 3000) is used. With chemical disinfection, there is a risk that disinfectant residues may be present on the instrument components.
  - A program suitable for the instrument, with adequate rinse cycles, is selected.
  - Sterile water or water with a low microorganism count (max. 10 germs per ml) and low endotoxin count (max. 0.25 endotoxin units per ml) is used for rinsing.
  - Drying air is filtered.
  - The CDM is serviced and tested at regular intervals.

**Suitable cleaning agents**

- Ensure that the selected cleaning agent system fulfils the following requirements:
  - The cleaning agent is suitable for the vessel sealing instrument.
  - If thermal disinfection is not used, a suitable disinfectant with proven effectiveness (e.g. DGHM or FDA approval or CE mark) and compatible with the cleaning agents is also used.
8 Cleaning

- The chemicals that are used are compatible with the instrument components (see section 8.9, page 40).
  - Follow the manufacturer's instructions with regard to the concentration and exposure time of the cleaning and disinfection products.

Cleaning and disinfection

1. Place the reprocessing basket in the CDM and start the program.
2. After the program is finished, remove the cleaning and reprocessing basket from the CDM.
3. Detach the cleaning adapters in the reverse order of attachment (see section 8.5.1, page 33).
4. Use filtered compressed air to dry the instrument components and remove any residual moisture.

NOTE

Risk of handle damage due to compressed air

- Restrict compressed air pressure to 3 bar or less for handle drying

8.6 Inspection

These products are subject to wear when used as intended, depending on the intensity of use. This wear arises from the design and construction of the instruments and is unavoidable.

Replace the product if it shows externally visible defects or does not function as described in this manual. Please advise the manufacturer or the manufacturer’s authorized representative in such cases.

- After cleaning, visually inspect each of the instruments and test them for proper operation.
- Replace any damaged parts.

DANGER

Risk of patient burns with brittle or defective insulation

- Replace instrument components with damaged insulation.
8 Cleaning

Handle

1. Check the ratchet for ease of motion.
   - If the handle is sluggish, lubricate it with a paraffin/white oil-based, biocompatible and steam-sterilisable (steam-permeable) care product (e.g. the special oil spray from Dr. Schumacher GmbH or comparable).
   Care products containing silicone must not be used.
   To lubricate the handle, it must be cooled down to room temperature. Then spray each 1 second into the openings of the handle marked below. By moving the actuating lever, the product will be evenly distributed. Remove superfluous care product on the surface with a lint-free cloth.

2. Check the jaw holder for damage and corrosion.

Jaw

1. Check the electrode surfaces and the blade groove for cleanliness and damage.
2. Check the cable in the joint area of the jaw for damage.

HF cable

1. Check the connector for damage and corrosion.
2. Inspect the insulation for damage.
8.7 Packing

Sterilization in the transportation packaging is not allowed.

The packaging must meet the following requirements:

- EN (ANSI AAMI) ISO 11607 / EN 868-2...10 (formerly EN 868 / ANSI AAMI ISO 11607)
- Suitable for steam sterilization (resistant to temperatures up to 137°C, sufficient steam permeability)
- Regular maintenance (sterilization container)
  - Check the instrument components for completeness.
  - Autoclave the handle only in the unlatched position.
  - Place the components in the reprocessing basket as shown in the following figure:

![Diagram showing the instrument components and reprocessing basket]

- Pack the reprocessing basket with the components in a suitable disposable sterilization package and/or a suitable sterilization container.

8.8 Autoclaving

**NOTE**
Risk of destruction of the vessel sealing instrument from hot-air sterilization

- Use a suitable sterilization method.

Use only steam sterilization with the following specifications:

- Fractional vacuum method (with adequate device drying)
• Compliant with EN 13060 or EN 285
• Validation in accordance with EN ISO / ANSI AAMI ISO 17665 (formerly EN 554 / ANSI AAMI ISO 11134) (valid IQ/OQ (commissioning) and product-specific performance assessment (PQ))
• Maximum sterilization temperature 134°C plus tolerance in accordance with EN ISO / ANSI AAMI ISO 17665 (formerly EN 554 / ANSI AAMI ISO 11134)
• Minimum sterilization requirement:
  • 20 minutes at 121°C
  • 3 minutes at 132/134°C

Using the less effective gravitation method must be secured by means of additional validation (longer sterilization times may be necessary).

The manufacturer accepts no responsibility whatsoever for the use of other sterilization methods, such as sterilization using ethylene oxide, formaldehyde, radiation or low-temperature plasma.

1. Observe the following if such methods are used:
   • EN ISO 14937 / ANSI AAMI ISO 14937;
   • Standards relevant to the method.

2. Verify the suitability and effectiveness of the method, taking into account the specific product geometry in the context of validation (including investigation of sterilization medium residues if appropriate).

8.9 Recommended operating supplies

BOWA recommends the use of neutral to slightly alkaline cleaning agents or cleaning and disinfection agents free from potentially harmful ingredients. Alcoholic and/or aldehydic ingredients may be permissible, depending on the concentration.

Pretreatment in an ultrasonic bath

The suitability of the vessel sealing instruments for effective pretreatment in an ultrasonic bath (5 minutes) with the use of an aldehyde-free combined cleaning and disinfection product (Gigasept Instru AF) has been demonstrated by BOWA.
Automatic cleaning

The suitability of the vessel sealing instruments for effective cleaning and/or disinfection with an automated method (90°C, 5 minutes) and an alkali cleaning product with a surfactant additive (neodic MediClean forte) has been demonstrated by BOWA.

The manufacturer accepts no responsibility for the use of other cleaning and disinfection products.

9 Storage

1. Store the vessel sealing instrument in a location where it is protected against:
   - strong mechanical stresses such as shocks, falling or blows
   - direct exposure to sunlight
   - X-ray radiation
   - heat sources

2. Store the instrument in a dry place at room temperature.

The storage life of the sterilized vessel sealing instrument depends on the type of packaging and the storage conditions.

The shipping box is not intended for storing the device.

10 Transport

1. Observe during transport of the vessel sealing instrument that it is protected against:
   - strong mechanical stresses such as shocks, falling or blows
   - direct exposure to sunlight
   - X-ray radiation
   - heat sources

2. Transport the instrument in a dry environment.
11 Technical specifications

<table>
<thead>
<tr>
<th>Technical specifications</th>
</tr>
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<tbody>
<tr>
<td><strong>Maximum voltage</strong></td>
</tr>
<tr>
<td><strong>Approved HF device</strong></td>
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<td></td>
</tr>
<tr>
<td></td>
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<tr>
<td><strong>Approved modes</strong></td>
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</tbody>
</table>

12 Disposal

**DANGER**

Infection hazard

To avoid spreading germs and infections, disinfect the instrument before it leaves the hospital or surgical practice.

The medical product, packaging material and accessories must be disposed of in accordance with any applicable country-specific regulations and laws.
### 13 Symbols on packaging

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>REF</td>
<td>Catalogue number</td>
</tr>
<tr>
<td>LOT</td>
<td>Batch</td>
</tr>
<tr>
<td>QTY</td>
<td>Quantity</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Expiry date</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Sterilized using ethylene oxide</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Single use only</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Do not resterilize</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Do not use if packaging is damaged</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Keep away from sunlight</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Keep dry</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>CE mark and identification number of notified body</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Conforms to Russian standards</td>
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