OPERATING MANUAL Bipolar forceps

Item no. / Designation
605-xxx Bipolar forceps
607-xxx Bipolar non-stick forceps

Medical Devices Directive
This device complies with Directive 93/42 EEC regarding medical devices.

1 Intended use
Indications
Bipolar forceps and used for electrosurgical coagulation in surgical procedures.

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

HF devices / Power settings
The maximum permitted voltage is 550 Vp.
The instrument is fundamentally intended to be used with a bipolar coagulation current.

Connection combinations
The instrument is intended to be used in combination with the following cables: 101-140, 351-040, 101-040, 353-040, 287-040.
Alternatively, the following cables may also be used: 351-051, 101-00, 353-050, 287-050.
In Autostart mode, the bipolar forceps may only be used with a bipolar connection cable with a maximum length of 4.5 meter.

2 Safety Instructions

2.1 Device specific
1. Sterilise goods supplied in non-sterile form before use. Maximum permissible sterilisation temperature 137°C.
2. Hot-air sterilisation is prohibited.
3. The instrument must be checked for damage after preparation and before use.
4. If there is any damage, the instrument may no longer be used.
5. Pay attention to correct cleaning, disinfection and sterilisation.
6. The polished noble metal tips of the bipolar forceps can become tarnished, similar to silver. This does not impair their normal operation.
7. The instrument must not be stressed beyond its mechanical limits.
8. Follow the user instructions for the HF generator.
9. Follow the user instructions for the connecting cable.
10. Repair and/or maintenance is not permitted.

2.2 Application specific
1. The user must be trained and competent in the basics, the rules of application and the risks of HF surgery.
2. Instruments must only be used by trained medical staff.
3. Do not use for the preparation of metallic implants, such as stents.
4. Do not use on the heart, on the central circulatory system or on the central nervous system.
5. Do not use for the contraceptive coagulation of the Fallopian tubes.
6. The operation area must be free of explosive gases or inflammable fluids and materials.
7. Consult a cardiologist before using HF surgery if the patient has a pacemaker.
8. The instrument must not come into contact with any other uninsulated instruments or objects.
9. Follow the recommended power settings and maximum voltage.
   Always select the minimum necessary power.
11. Perform coagulation only when the contact surfaces are visible.
12. Caution: When the Autostart function is used, HF activation occurs on contact with tissue.
13. To avoid patient injury in the event of accidental HF activation, do not lay active HF instruments on the patient.
14. Soiled forceps tips may lead to insufficient coagulation.
15. Immediately after the HF power has been switched off, the tips may still be hot enough to cause burns.
16. For cleaning of the active electrodes, either Autostart mode must be disabled or the instrument must be disconnected from the generator.
17. The connected instrument extends the BF or CF application part of the HF generator being used.
2.3 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 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, or
► 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.

3 Preparation

Ensure that insulated parts do not come in contact with hard, pointed or heavy objects during preparation, as such objects may damage the insulation and render the device unusable.

Non-stick forcep tips (REF 607-xxx) may not be cleaned with metallic brushes, abrasive substances, or other media or tools which may damage the surface of the instrument. Damp swabs or similar should be used to clean the tip area.

<table>
<thead>
<tr>
<th>Preparation cycles</th>
<th>75</th>
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<tr>
<td>Soaking</td>
<td>Soak the instrument immediately after use, or no later than 2 hours after use. Use only aldehyde-free disinfectants (recommended: Gigasept Instru AF) designed for the disinfection of instruments (e.g. with DGHM or FDA approval or CE mark). Place the instrument in an ultrasonic bath for at least 5 minutes. Use a cleaning solution to soften coagulation residues (encrustations), and remove them with a soft cleaning cloth.</td>
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<tr>
<td>Cleaning/Disinfection</td>
<td>Recommendation: Machine cleaning in a cleaning/disinfection machine and thermal disinfection. Parameters: minimum 5 minutes at 90°C or A0 value &gt; 3000. BOWA recommends the use of neutral to slightly alkaline (pH 9.5 – 11.5) cleaning agents or chemical agents suitable for medical devices made from plastic and metal. Alcoholic and/or aldehydic ingredients may be permissible, depending on the concentration. If necessary, blow off with filtered compressed air. Only dry the devices with compressed air at pressures below 3 bar, to avoid possible damage. The manual method is not suitable for these devices.</td>
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<tr>
<td>Effective cleaning verified by BOWA</td>
<td>Machine cleaning (90°C, 5 minutes) using an alkaline cleaning agent with surfactant additive (Neodisher MediClean forte)</td>
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<tr>
<td>Autoclaving</td>
<td>Fractionated vacuum method Retention time: 3-20 minutes; Sterilisation temperature: 134–137°C</td>
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The manufacturer accepts no responsibility if other types of cleaning and disinfection agents are used. Follow the recommendations of the cleaning agent manufacturer.

4 Operation, storage and transport

Temperature: -20 to +50°C; Relative humidity: 0 - 75%, non-condensing; Air pressure: 500 - 1060 hPa.

All forceps must be handled with the greatest possible care during transportation. This applies in particular to fine tips and other vulnerable areas. Protect sterilised devices from exposure to direct sunlight during storage. It is recommended to keep the devices in the original packaging until use.

5 Disposal

The medical device, packaging material and accessories must be disposed of in accordance with any applicable country-specific regulations and laws.