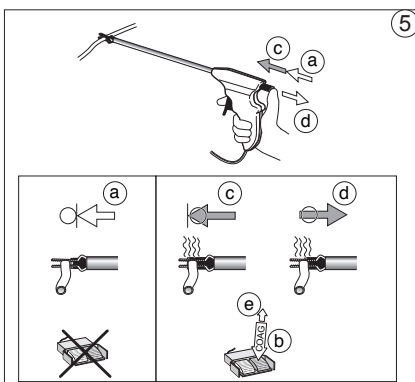
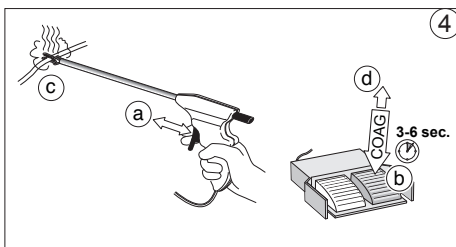
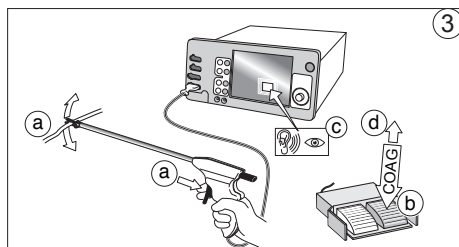
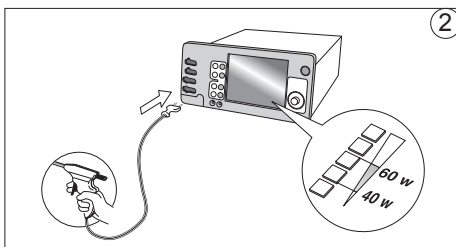
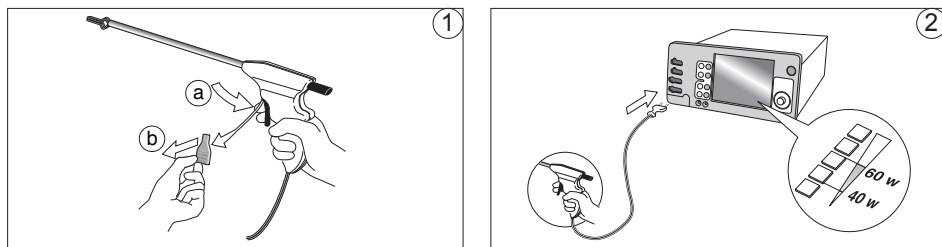




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**Caution:**  
**Federal Law (USA) restricts this device to sale by or on the order of a physician skilled in laparoscopic surgical techniques.**



## LiNA PowerBlade™

Ref: 5005, 5005-160, 5005-420, 5005-C, 5005-C-160, 5005-C-420, 5005-E, 5005-E-160, 5005-E-420, 5005-E-C, 5005-E-C-160, 5005-E-C-420, 5010, 5010-160, 5010-E, 5010-E-160, 5005-Y, 5005-Y-160, 5005-Y-420, 5005-Y-C, 5005-Y-C-160, 5005-Y-C-420, 5010-Y, 5010-Y-160

### Important:

This information is provided for the use of LiNA PowerBlade™. It is not intended to demonstrate laparoscopic techniques or procedures. Consult published and recognized medical literature for appropriate techniques, complications, and hazards prior to doing any laparoscopic procedure. Consult the instructions for use provided by the manufacturer of the electrosurgical generator and/or laparoscope and/or cables for instructions and warnings concerning said devices.

### Intended use:

The LiNA PowerBlade™ is intended for use in open or laparoscopic surgery where grasping, coagulating and transecting is indicated.

### Patient population:

All patient groups which require minimally invasive or open surgery.

### Product description:

The LiNA PowerBlade™ is a single use, multifunctional bipolar forceps intended for grasping, coagulation and cutting in open and laparoscopic surgery. It is an electrically powered endoscopic surgical instrument manually controlled by the surgeon via foot pedal and ESU settings. Grasping, coagulation and cutting is necessary for the surgeon to dissect and maintain clear vision of the structures operated upon. Coagulation serves to prevent or stop bleeding while cutting serves to divide normal, pathological or scarred tissue in order to progress the dissection.

### Warnings:

- Noncompliance with the instructions for use may lead to severe injury of patient or user and lead to damage or failure of the product. Before using this product carefully read and make sure the instructions for use are understood. This product may only be used by qualified and trained personnel.
- The LiNA PowerBlade™ is supplied sterile using a radiation process. Do not use the product if the sterile barrier is damaged.
- Inspect the LiNA PowerBlade™ for breaks, cracks, nicks or other damage prior to use. If damaged, do not use.
- LiNA PowerBlade™ is designed for single use. Any reprocessing may impede the functions of the device. Reusing single use devices may also increase the risk of cross contamination.
- Always verify that the active part of the jaws is not in contact with any organ other than the requested (e.g. uterus, vessel) before activating the generator.
- Do not activate the LiNA PowerBlade™ if it is not possible to visualize the jaws.
- Do not use LiNA PowerBlade™ on vessels larger than 7mm in diameter.
- Do not place the LiNA PowerBlade™ in contact with any metal objects during use (e.g. staples, clips, retractors).
- Do not place the LiNA PowerBlade™ near or in contact with flammable materials or liquids (e.g. drapes, gauze, alcohol).
- Do not use a scalpel or any sharp metal instrument to clean the jaws.
- Do not connect the LiNA PowerBlade™ to a monopolar outlet on the generator. Always use a bipolar outlet.
- Do not use auto-coagulation. Always use manual coagulation.
- Do not use laparoscopic ports which exceed an inner diameter of 5,7mm for the 5mm LiNA PowerBlade™.
- After use, dispose of the product and packaging in accordance with hospital, administrative and/or local government policy.

### Precautions:

Precautions should be taken when the patient has any implanted electronic device (IED). The perioperative team should consult with the team managing the implanted device before surgery and as needed. When PowerBlade™ is activated it should be kept more than ½ inch (1 cm) from the IED.

### Instruction for use:

#### 1. Unpacking

Remove the LiNA PowerBlade™ from the blister package.

- Pull the trigger.
- Remove the yellow tag from the trigger.

#### 2. Generator settings

When using **REF 5005 or 5010**: Connect the 4mm male plugs to the bipolar outlet on the generator. Use a cable adapter if necessary. When using **REF 5005-E or 5010-E**: Connect the European connector to a standard bipolar cable which fits your generator. Connect the bipolar cable to the bipolar outlet on the generator. When using **REF 5005-Y or 5010-Y**: Connect the bipolar plug with fixed 29mm distance to the bipolar outlet on the generator. Use a cable adapter if necessary. Adjust generator settings to 40-60W. Always use the lowest power setting available to achieve the desired surgical effect.

#### 3. Test

Test the LiNA PowerBlade™ and generator:

- Pull the trigger to ensure that the jaws separate.
- Activate the foot pedal.
- Observe that while keeping the jaws separated, the generator will operate "COAG" (light & sound).
- Release the foot pedal.

#### 4. Coagulation

- Pull the trigger and grasp the tissue with the jaws. Release the trigger making sure that the tissue is well placed in the center of the jaws. Grasp only tissue between the flat portions of the jaws. Over grasping can lead to insufficient cutting and coagulation.
  - Activate the foot pedal to start the coagulation. Keep the foot pedal activated until sufficient coagulation has been achieved. (Approx 3-6 sec.)
  - You will observe smoke from the coagulation site.
  - Release the foot pedal.
- During coagulation you might notice a crisp sound and a slight vibration in the handle. The sound and vibration is amplified in the carbon tube and is a harmless occurrence indicating that the tissue is being coagulated.

#### 5. Cutting / transecting

- By pressing the button on the back of the handle, move the cutting electrode forward until it is ready to enter the tissue.
- Activate the foot pedal.
- By an additional pressure on the button on the back of the handle, move the cutting electrode forward through the tissue.
- When the cutting electrode is in complete forward position, start moving the cutting electrode back again by slowly relieving the button on the back of the handle. For sufficient cutting / transecting keep the foot pedal activated until the cutting electrode is back in its starting position. Please notice that the cutting / transecting procedure is performed electro-surgically, not mechanically which is why no extra force is needed when moving the cutting electrode forward.
- Release the foot pedal. Make sure that haemostasis has been obtained before moving on to the next procedure.

### Cleaning the jaws and the cutting electrode

It is recommended to clean the jaws several times during the procedure to ensure optimal coagulation. Remove the LiNA PowerBlade™ from the patient and gently clean the jaws and the cutting electrode with e.g. a piece of cloth with chlorine hexamine or sterile water.

### Reporting:

Any serious incident that has occurred in relation to the device should be reported to the LiNA Medical ApS and the competent regulatory authority of the country in which the user and/or patient is established.

Country of origin: Poland.  
CE marking 2007.

