Instructions for Use for CAIMAN™ Instrument (12 mm x 24 cm)

Item #: PL730SU

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

The Lektrafuse Radio Frequency (RF) Generator Instructions for Use (IFU) is supplied as a separate document. The Generator IFU contains detailed information describing the Lektrafuse RF System components, generator setup, guide to operation, maintenance, troubleshooting, and specifications.

Please read the IFU prior to operation of the Lektrafuse RF Generator.

**BRIEF SYSTEM DESCRIPTION**

The CAIMAN Instrument contained in this package is a sterile, single-use component of the Lektrafuse System and is designed to deliver radiofrequency (RF) energy from the RF Generator. The CAIMAN Instrument can only be used in conjunction with the dedicated Lektrafuse RF Generator.

The CAIMAN Instrument is only compatible with the Lektrafuse™ RF Generator, which supplies a maximum voltage of 115Vrms.

**INDICATION FOR USE**

The CAIMAN Instrument is a dedicated bipolar electrosurgical instrument intended for use in general surgical and gynecologic procedures where ligation and division of vessels is desired. The instruments create a seal by the application of bipolar electrosurgical RF energy (coagulation) to vascular structures (vessels) interposed between the jaws of the device. A cutting blade is actuated for the division of tissue.

The indications for use include general surgical procedures, (including urologic, vascular, thoracic, and thoracoscopic), and gynecological procedures where ligation and division of vessels is performed. These procedures include: hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, bowel resections, and oophorectomy etc., or any procedure where vessel ligation (cutting and sealing), tissue grasping, and dissection is performed.

The device can be used on vessels up to and including 7 mm and bundles as large as will fit in the jaws of the instrument.

The CAIMAN Instrument has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the system for these procedures.

**CONTRAINDICATIONS**

The CAIMAN Instrument is not effective for use in tubal sterilization or tubal coagulation for sterilization purposes. Do not use the CAIMAN Instrument for these procedures.

**WARNINGs**

- The CAIMAN Instrument is intended for use ONLY with the dedicated Lektrafuse RF Generator. Use of the CAIMAN Instrument with any other generators produced by other manufacturers may result in injury to the patient and/or damage to the Instrument.

- Only properly trained personnel should use the CAIMAN Instrument.

- The CAIMAN Instrument should not be used when, in the judgment of the treating physician, the RF procedures would be contrary to the best interests of the patient.

- The CAIMAN Instrument is not effective for use in tubal sterilization or tubal coagulation for sterilization purposes. Do not use the CAIMAN Instrument for these procedures.

- The CAIMAN Instrument is intended for sealing and dividing tissues, including ligaments and vessels, or any procedure where vessel ligation (cutting and sealing), tissue grasping, and dissection is performed.
• Use caution during surgical cases in which patients exhibit certain types of vascular pathology (atherosclerosis, aneurismal vessels, etc.). For best results, apply the seal to unaffected vasculature.

• Do not use the CAIMAN Instrument on vessels in excess of 7 mm in diameter.

• Use extreme care when inserting and removing the CAIMAN instrument through a cannula to avoid possible damage to the devices and/or injury to the patient.

• Inspect the Instrument and cable/cords for breaks, crack, nicks, or other damage before use. If damaged, do not use. Failure to observe this caution may result in injury or electrical shock to the patient or surgical team or cause damage to the Instrument.

• Position CAIMAN Instrument cords to avoid contact with the patient or other leads. Do not wrap cords around metal objects. This may induce currents that could lead to shocks, fires, or injury to the patient or surgical team.

• Examine all connections to the Lektrafuse RF Generator and all Instruments before using. Improper connection may result in arcs, sparks, accessory malfunction, or unintended surgical effects.

• Do not use the CAIMAN Instrument in the presence of flammable anesthetic or other flammable liquids, gases, or other flammable materials.

• Where the CAIMAN Instrument is utilized, prevent the accumulation of oxygen or other oxidizing gases.

• The risk of igniting flammable gases or other materials is inherent in electrosurgery and cannot be eliminated by device design. Precautions must be taken to avoid contact of the CAIMAN Instrument electrodes and flammable materials and substances, including some forms of anesthetic or skin preparation agents, flammable materials and substances produced by natural processes within body cavities, and flammable materials and substances such as surgical drapes or other materials present in the operative field.

• During a seal cycle, energy is applied to the area between the instrument jaws. This energy may cause water to be converted into steam. The thermal energy of steam may cause unintended injury in close proximity to the jaws. Care should be taken in surgical procedures occurring in confined spaces in anticipation of this possibility.

• Studies have shown that smoke generated during electrosurgical procedures may be harmful to surgical personnel. These studies recommend using an appropriate surgical mask and adequate ventilation of the smoke by use of a surgical smoke evacuator or other means.

• Use the CAIMAN Instrument with caution in the presence of an internal or external pacemaker. Interference produced by electrosurgical devices can cause devices such as pacemakers to enter an asynchronous mode or can block the pacemaker effect entirely. Consult with the pacemaker manufacturer or hospital biomedical engineering personnel for further information.

• Use the CAIMAN Instrument with caution in the presence of an internal cardiac defibrillator (ICD). Electrosurgery may cause multiple activations of ICDs. Consult with the ICD manufacturer or hospital biomedical engineering personnel for further information when use of electrosurgical application is planned in patients with ICDs.

• The CAIMAN Instrument has a marker at the distal tip of the jaws which indicates the furthest extent to which the cutting blade can be advanced. Any tissue distal to this marker will NOT be cut during the dissection process.

• Contact between any active instrument electrode and any metal object (hemostats, staples, clips, retractors, etc.) may increase current flow and can result in unintended surgical effects such as an effect at an unintended site or insufficient energy deposition.

• Do not activate the Lektrafuse RF Generator until the Instrument has been applied with the proper jaw pressure. Activating the system before this is done may result in improper sealing and may increase thermal spread to tissue outside the surgical site.

• Do not activate the Lektrafuse RF Generator in an open circuit condition. Activate the generator only when the instrument is near or in direct contact with the target tissue to reduce the possibility of unintended burns.
Always keep the external surface of the instrument jaws away from adjacent tissue while activating the Lektrafuse RF Generator. Do not activate RF energy if the jaw cannot be visualized.

Do not activate the CAIMAN Instrument while the instrument jaws are in contact with, or in close proximity to, other conductive instruments including metal cannulas as localized burns to the patient or physician may occur.

PRECAUTIONS

- Avoid placing fingers in the handle ratchet mechanism (between the handle and the jaw closure lever). Injury to the User may result.
- The CAIMAN Instrument must be disposed of properly in accordance with the applicable national/local/state environmental laws.
- The external surfaces of the CAIMAN Instrument jaws may remain hot enough to cause burns after the RF current is deactivated.
- Inadvertent activation or movement of the RF activated CAIMAN Instrument outside of the field of vision may result in injury to the patient.
- Do not open and close the jaws during the RF sealing cycle. An incomplete seal may occur. Reseal with RF energy prior to division.

USE OF THE LEKTRAFUSE RF GENERATOR SYSTEM DURING SURGERY

PATIENT AND OPERATING ROOM SAFETY

The safe and effective use of electrosurgical equipment is largely dependent upon factors solely under the control of the user and associated operating room personnel. There is no substitute for a properly trained and vigilant surgical team. It is important that the operating instructions supplied with the Lektrafuse RF Generator IFU be read, understood, and followed.

The CAIMAN Instrument (12 mm x 24 cm) is designed for general procedures, (including urologic, vascular, thoracic, and thoracoscopic), and gynecological procedures where ligation and division of vessels is performed.

The device can be used on vessels up to and including 7 mm and bundles as large as will fit in the jaws of the Instrument.

OPERATION OF THE Lektrafuse SYSTEM

The Lektrafuse RF System is designed to seal and divide tissue with a single application (50 mm represents complete coverage of the CAIMAN Instrument jaws by tissue). After first performing necessary tissue dissection; the user determines length of tissue to be sealed and divided with any individual application of the CAIMAN Instrument (within the range of 10-50 mm), and where within the CAIMAN Instrument jaws the tissue is to be placed.

CAUTION: The selected tissue should not be bunched, folded, or layered within the Instrument jaws. Failure to correctly position the tissue within the Instrument jaws may result in inadequate tissue sealing and/or division.

TISSUE AND VESSEL SEALING SETTINGS

Lektrafuse’s Technology has the capability that enables the user to seal and divide 10-50 mm length of variable thickness tissue. Aesculap, Inc. has achieved this through a series of proprietary designs.

The jaw design optimizes the pressure between the two jaws resulting in uniform force distribution along the tissue length. This allows the user to uniformly and consistently seal and divide any length of tissue of varying thickness or compressibility.

In addition, the RF Generator software is capable of sensing electrical parameters to determine the level of tissue coverage and the thickness of such tissue to optimize the sealing process. Based on these parameters, the risk of arcing is reduced.

Therefore the energy settings allow for uniform and consistent sealing regardless of the degree of vascularity, vessel size, and length of tissue being sealed.
Sealing Duration and Power Setting do not require any User adjustment. The sealing parameters are monitored by the software based on:

- Impedance
- RF Voltage
- RF Current

The Lektrafuse technology allows the CAIMAN Instrument to be used on vessels up to and including 7 mm in diameter.

If sealing conditions are not met, a “Regrasp Indicator” series of audible tones is triggered by the Lektrafuse RF Generator to inform the user that adequate tissue sealing may not have been achieved following the delivery of RF energy. An additional tissue sealing cycle may then be performed by the user, or the user may remove the CAIMAN Instrument and divide the sealed tissue manually (using surgical scissors).

When RF energy is applied, the maximum RF cycle is 17.5 seconds.

The energy setting and application duration has been validated by performing bench, animal and software validation.

SET-UP (Connecting the CAIMAN Instrument to the Lektrafuse RF Generator)

- Open the CAIMAN Instrument package using standard sterile technique.
- The CAIMAN Instrument RF cable ends in a connector; directional arrows are indicated on one side. On the left front of the Lektrafuse RF Generator is the connector port with a red dot in the superior (12 O’clock) position. Align the arrows on the cable connector with the red dot on the connector port and push the connector into the connector port. If you feel any resistance, stop pushing, realign the arrows and the red dot, and try again. There should be little to no resistance if the connector is correctly aligned within the connector port. Advance the connector fully into the connector port, until no further connector may be advanced. Inadequate or incomplete advancement of the connector into the connector port may result in failure of the System to correctly or adequately operate. If the connector is correctly advanced into the connector port, the green ring encircling the connector port on the Lektrafuse RF Generator will illuminate.

STEP BY STEP USE OF THE CAIMAN INSTRUMENT:

Rotating Instrument Shaft and Jaws

- Turn the rotator (a) on the Instrument until the jaws are in the required position. A black line on the rotator designates when the CAIMAN 24 jaw is in the midline or horizontal position.

Articulating Instrument Jaw Wrist

- Turn the articulation lever (b) with a left and right movement to the required position and the jaw wrist (c) will move accordingly.
  1. The CAIMAN Instrument allows jaw rotation via the rotator (a), and articulation with right and left movement of the jaw articulation (c) via the articulation lever (b).
  2. Maneuver the CAIMAN Instrument jaw to the desired tissue by turning the rotator (a) or pulling/pushing right and left on the articulation lever (b).
  3. Place the tissue in the CAIMAN Instrument jaws.
  4. With the selected tissue (10-50 mm in length) positioned in the CAIMAN Instrument, squeeze (close) the Jaw Closure Lever (d) (the jaws will close) until the Lever palpably locks into the closed position. The jaws will remain locked.

Note: If not satisfied with the selection or placement of tissue within the jaws, gently squeeze the Jaw Closure Lever (d), opening the jaws and reposition the tissue selected in the jaws.

- To apply RF energy, press and release the red RF button (f) on the handle, the Foot Pedal, or the RF Delivery Control Button (on the front of the RF Generator).

- The termination of audible tones indicates completion of tissue sealing and is accompanied by the loss of illumination of the blue ring encircling the RF Delivery Control Button on the RF Generator.
7. If division (cutting) of the sealed tissue is desired, fully retract the Cutter Lever (e) located on the bottom of the Instrument by pressing towards the handle in a trigger-like motion. The Cutter Lever automatically returns to its original position.

8. To open the CAIMAN Instrument jaws (following sealed tissue division, or following tissue sealing if division is not required), gently squeeze the Jaw Closure Lever (d) to unlock as the jaw closure lever returns to its former open position.

9. Upon removal of the Instrument away from the dissected tissue, visually inspect the jaw surfaces. If cauterized tissue and/or blood is readily visible on the CAIMAN Instrument electrodes, gently remove the material using a sterile surgical pad/gauze dampened with sterile water.

REGRASP INDICATOR CAUTION: The Lektrafuse RF System is designed to identify electrical characteristics indicating potentially inadequate sealing of the tissue within the instrument jaws. If such potentially inadequate sealing is identified, a unique and distinct audible series of tones will immediately sound from the RF Generator following automatic termination of the audible tones associated with tissue sealing. This unique and distinct tone is a Regrasp tone and is accompanied by the illumination of the amber Regrasp indicator light on the front of the RF Generator and a Regrasp message on the RF Generator Screen.

If a Regrasp occurs,

1. do not divide the tissue with the cutter
2. open the instrument jaws
3. visually examine the sealed tissue
4. manually divide the tissue with surgical scissors

OR

1. reapply the jaws to the tissue and lock the jaws in place
2. deliver an additional cycle of RF, which may result in a normal seal process (which can then be followed by routine sealed tissue division, jaw release, and instrument removal)

If a Regrasp reoccurs, the sealed tissue should not be divided, the jaws should be released, and the sealed tissue divided manually with surgical scissors and hemostasis achieved where required.

A single press and release action on either the Foot Pedal, RF Delivery Control Button (on the front of the RF Generator), or the RF Button (on the Lektrafuse Instrument) will (1) automatically terminate the Regrasp tones, amber Regrasp indicator light on the front of the RF Generator, and the Regrasp message on the RF Generator Screen; and (2) setup the System for the next standard tissue sealing and division process.

DISCARD USED INSTRUMENT

Discard the CAIMAN Instrument after use in accordance with hospital policy for biohazards and sharps. DO NOT RESTERILIZE.
Functional Operation of the CAIMAN Instrument (12 mm x 24 cm)

The below figure identifies the operational rotator/levers/button used to operate the CAIMAN Instrument

- **a)** Rotator
  - Rotating shaft and jaws +/- 150°

- **b)** Articulation Lever
  - Right and Left

- **c)** Jaw Articulation

- **d)** Jaw Closure Lever
  - Jaw Clamping
  - (Spring Opening)

- **e)** Cutter Lever
  - Cutting Blade Deployment
  - (Spring Return)

- **f)** RF Button
  - ON/OFF Button

- **Jaw Markers**
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## Additional Departmental Approval

(See SOP-AIS-5000346/SOP-AIC-5000365 Attachment 1- DEPARTMENT DOCUMENT APPROVER/REVIEWER MATRIX)

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