Instructions for Use for Caiman® Seal and Cut Technology Instruments
Caiman® 5 and Caiman® 12

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.

Description of Symbols

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Legend

Instrument
1 RF activation button
2 Rotation wheel
3 Jaw articulation
4 Moveable jaw part with marking
5 Articulation actuation lever
6 Blade actuation lever
7 Jaw part actuation lever
8 RF cable with connector

Generator
9 RF activation button
10 Foot switch connection socket
11 Regrassp signal lamp
12 Display
13 Error signal lamp
14 Instrument connection socket
15 “Power on” indicator light
16 Foot control switch

BRIEF SYSTEM DESCRIPTION
The Caiman Instrument contained in this package is a sterile, single-use component of Aesculap Seal and Cut Technology and is designed to deliver radiofrequency (RF) energy from the Lektrafuse 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 240Vp.

INDICATIONS FOR USE
Caiman Seal and Cut Technology consists of dedicated bipolar electrosurgical instruments intended for use in general surgery and gynecologic surgical 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 structure (vessels) interposed between the jaws of the device. A cutting blade is actuated for the division of tissue.

The Caiman 12 Plus (44cm) and the Caiman 5 (36cm and 44cm) are indicated for laparoscopic procedures and the Caiman 12 Plus (24cm) and Caiman 5 (24cm) are indicated for open procedures. The indications for use include general surgical procedures, (including urologic, vascular, thoracic, and thorascopic), and gynecological procedures where ligation and division of vessels is performed. These procedures include: vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, bowel resection, and oophorectomy etc., or any procedure where vessel ligation (seal and cut), tissue grasping, and dissection is performed. The devices can be used on vessels up to and including 7mm and bundles as large as will fit in the jaws of the instrument.

Caiman Seal and Cut Technology 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

- Inspect the Caiman Instrument for damages. Do not use the instrument if the Tyvek tray seal has been compromised or if there is any evidence of damage, such as broken or missing components. Either contact Aesculap, Inc. for a replacement or dispose of the Caiman Instrument abiding all regulation on disposing disposable medical instruments.
- 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.
- 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 anesthetics or oxidizing gases (such as nitrous oxide (N2O) and oxygen) or in close proximity to volatile solvents (such as methanol or alcohol), as explosion may occur.
- Do not place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.
- When not using instruments, place them in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.
- Do not place the vessel and/or tissue in the jaw hinge. Place the vessel and/or tissue in the center of the jaws.
- Do not use energy based devices to transect seals, such as electrosurgical pencils or ultrasonic scalpels.
- Do not attempt to seal over clips or staples or contact metal objects (e.g. retractors). Contact between an active electrode and any metal objects may result in alternate site burns or incomplete seals.
- Do not use with hybrid trocar systems, i.e., a combination of metal and plastic cannula. This may result in alternate site burns due to capacitive coupling. Use only all-metal or all-plastic cannula trocar systems.
- Aspirate fluid from the area before activating the instrument. Conductive fluids (e.g. blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.
- Do not use in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g. cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.
- 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.
- Always use surgeon judgment to determine that seal quality is acceptable. If adequacy of the seal quality is in question, activate the RF generator to repeat the seal cycle.
- 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.

Do not articulate or rotate the device when the jaws are in the locked position.

Do not leave the jaw actuation lever in the locked position when the instrument is not in use.

**PRECAUTIONS**

- Keep the active electrodes clean. Build-up of eschar may reduce the instrument’s effectiveness. Do not activate the instrument while cleaning. Injury to operating room personnel may result. Clean jaw surface using a sterile surgical pad/gauze dampened with sterile water.
- Avoid placing fingers in the handle ratchet mechanism (between the handle and the jaw closure lever). Injury to the User may result.
- Carefully insert and withdraw Caiman Instrument from cannulas to avoid possible damage to the devices and/or injury to the patient. Ensure articulating devices are in the neutral position and are closed and locked before insertion and withdrawal.
- 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.
- Do not overfill the jaws of the instrument with tissue, as this may reduce device performance.

**ANIMAL TESTING**

Aesculap, Inc. conducted chronic animal studies to demonstrate the effectiveness of the Lektrafuse RF System with the Caiman Instrument for general surgery and gynecological procedures and the sealing of vessels up to and including 7 mm.

Three canines and one porcine were selected to undergo general surgical and gynecological procedures utilizing the Caiman Instrument to seal and divide vessels up to and including 7 mm. The vessels sealed ranged from 2-7 mm. A total of 115 visible vessels were sealed. The animals were survived for 21 days to determine if there was any leakage at the vessel occlusion site due to thermal injury and subsequent tissue necrosis and if any injuries to adjacent structures or organs had occurred.

The outcomes demonstrated no visible macroscopic vessel leaking and no injury or damage to adjacent structures or organs.

Potential adverse events from thermal spread that might cause or contribute to injury or damage to adjacent structures or organs were not observed in this study.

There is no animal predictive of how the device functions when used to seal vessels containing atherosclerotic plaque.

Clearance of the Caiman Instrument was not based on human clinical testing.
USE OF THE LEKTRAFUSE 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 Lektr Fuse RF Generator Operator’s Manual be read, understood, and followed.
The Caiman Instrument 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.

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
The software of the Lektr Fuse RF generator recognizes the Caiman 5 instruments and applies the corresponding device settings. The duration of the sealing process is controlled by the generator software.
The sealing process is started by tapping on an RF button once. The sealing process is interrupted by again tapping an RF activation button. The sealing parameters are monitored by the software based on:
- Impedance
- RF Voltage
- RF Current

The Lektr Fuse 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 Lektr Fuse 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.

SET-UP (Connecting the Caiman Instrument to the Lektr Fuse 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 Lektr Fuse 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 Lektr Fuse RF Generator will illuminate.

STEP BY STEP USE OF THE CAIMAN INSTRUMENT:
JawsNon-Articulating Instrument Jaw
- Turn the rotator (2) on the Instrument until the jaws are in the required position. A black line on the rotator designates when the Caiman Instrument jaw is in the midline or horizontal position.
Articulating Instrument Jaw Wrist

- Turn the articulation lever (5) with a left and right movement to the required position and the jaw wrist (3) will move accordingly.
  1. The Caiman Instrument allows jaw rotation via the rotator (2), and articulation with right and left movement of the jaw articulation (3) via the articulation lever (5).
  2. Maneuver the Caiman Instrument jaw to the desired tissue by turning the rotator (2) or pulling/pushing right and left on the articulation lever (5).
  3. Place the tissue in the Caiman Instrument jaws centering it between the black line at the base of the jaws and the black line on the tip of the jaws.
  4. With the selected tissue (10-50 mm in length) positioned in the Caiman Instrument, squeeze (close) the Jaw Closure Lever (7) (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 (7), opening the jaws and reposition the tissue selected in the jaws.
  5. To apply RF energy, either press the Blue RF button (1) on the handle, tap the Foot Pedal, or push the RF Delivery Control Button (on the front of the RF Generator).
  6. 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 (6) 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 (7) 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, or the RF Button (on the Caiman 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.

**AFTER SURGERY DISCARD USED INSTRUMENT**

Discard the Caiman Instrument after use in accordance with hospital policy for biohazards and sharps. **DO NOT RESTERILIZE.**

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