

LigaSure™

[REF] LF1823 Blunt Tip Open Sealer/
Divider

Nano-coated

5 mm – 23 cm

[REF] LF1837 Blunt Tip Laparoscopic
Sealer/Divider

Nano-coated

5 mm – 37 cm

[REF] LF1844 Blunt Tip Laparoscopic
Sealer/Divider

Nano-coated

5 mm – 44 cm

The LigaSure Blunt Tip Sealer/Divider is designed for use with Covidien electrosurgical generators that include vessel sealing capability. Please refer to the cover page for details on compatible generator models and software versions. If the software version on your generator is lower than required, contact Covidien about software upgrades.

These instructions assume that the operator is knowledgeable about correct set-up and operation of the associated Covidien generator. Refer to the generator user's guide for set up information and for additional warnings and precautions.

The instrument creates a seal by application of radiofrequency (RF) electrosurgical energy to vascular structures (vessels and lymphatics) or tissue bundles interposed between the jaws of the instrument. A blade within the instrument is surgeon actuated to divide tissue. Shorter shaft lengths are typically used for open procedures while longer shaft lengths are typically used for minimally invasive procedures.

Maximum rated voltage: 288 V_{peak}



Not made with natural rubber latex



Do not use if the leakage is equivalent to a lightning bolt



Type 1 applied part

Indications for Use

The LigaSure™ Sealer/Divider is a bipolar electrosurgical instrument intended for use in minimally invasive or open surgical procedures where ligation and division of vessels, tissue

bundles, and lymphatics is desired. The LigaSure Sealer/Divider can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and such surgical specialties as urologic, vascular, thoracic, and gynecologic. Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc.

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

Warning

This product cannot be adequately cleaned and/or sterilized by the user in order to facilitate safe reuse, and is therefore intended for single use. Attempts to clean or sterilize these devices without appropriate regulatory authorization may result in bio-incompatibility, infection, or product failure risks to the patient.

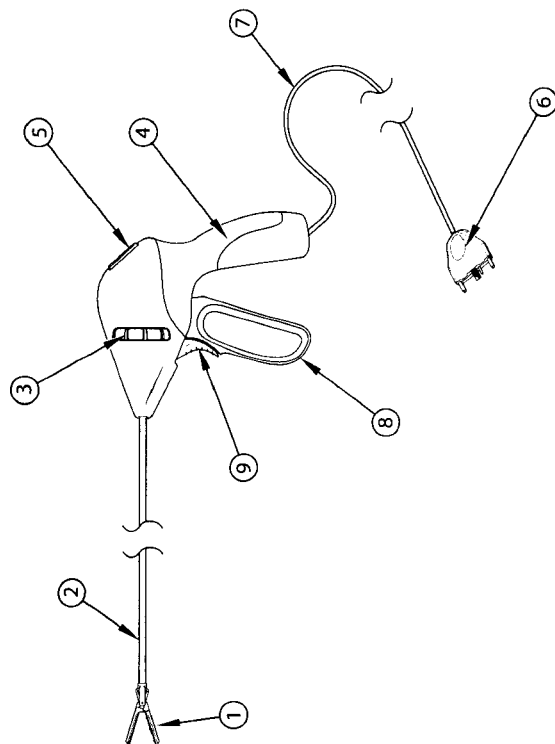
The instrument is intended for use ONLY with the Covidien equipment listed on the cover of this document. Use of this instrument with other generators may not result in the desired tissue effect, may result in injury to the patient or surgical team, or may cause damage to the instrument.

Do not use the LigaSure system unless properly trained to use it in the specific procedure being undertaken. Use of this equipment without such training may result in serious unintended patient injury.

Use the system with caution in the presence of internal or external pacemakers or other implanted devices. Interference produced by electrosurgical equipment can cause a pacemaker or other device to enter an unsafe mode or permanently damage the device. Consult the device manufacturer or responsible hospital department for further information when use is planned in patients with implanted medical devices.

When this instrument is used with an energized endoscope, the leakage current from the instrument and the endoscope are additive. The patient may be exposed to unexpected levels of leakage current if this instrument is used with an energized endoscope that is not type CF.

LF1823, LF1837, and LF1844 LigaSure Blunt Tip Sealer/Divider



- ① Jaws
- ② Shaft
- ③ Rotation wheel (gray)
- ④ Handle (gray and white)
- ⑤ Activation button (purple)
- ⑥ Connector (purple and white)
- ⑦ Cable
- ⑧ Lever (gray and white)
- ⑨ Cutting trigger (gray)

Precaution

The performance of this single-use device has been tested according to the expected conditions of a single surgical procedure. Subjecting the device to process steps, tools, and chemicals commonly used for reprocessing has been shown to degrade the nano-coating material on the active sealing surfaces. Degradation of the coating can lead to reduced performance, such as increased tissue adhesion.

Setup

Warning

Electric Shock Hazard – Do not connect wet accessories to the LigaSure system.

Position instrument cords to avoid contact with the patient or other cords. 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 LigaSure system and instrument connections before using. Improper connections may result in arcing, sparks, accessory malfunction, or unintended surgical effects.

Inspect the instrument and cords for breaks, cracks, nicks, or other damage before 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. If damaged, do not use.

Warning

In minimally invasive surgery, inspect the outer surfaces of the instrument before insertion through the cannula to ensure that there are no rough or sharp edges that could damage tissue.

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

The safe and effective use of RF energy depends on many factors solely under the control of the operator. There is no substitute for properly trained and vigilant personnel. It is important that the operating instructions supplied with this or any other medical equipment be read, understood, and followed.

Warning

Confirm proper LigaSure system settings before proceeding with surgery.

Do not use 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 ether or alcohol) as explosion may occur.

Because of concerns about the carcinogenic and infectious potential of electrosurgical by-products (such as tissue smoke plume and aerosols), protective eye wear, filtration masks, and effective smoke evacuation equipment should be used in both open and minimally invasive procedures.

Connect adaptors and accessories to the electrosurgical unit only when the unit is off or in standby mode. Failure to do so may result in injury or electrical shock to the patient or operating personnel.

Precaution

Inspect packaging for damage. If damaged, do not use.

If the generator provides multiple power settings, use the lowest power needed to achieve the intended effect.

1. Remove instrument from tray by firmly pulling on the handle (4). Do not pull on the instrument's jaws (1) or cable (7).
2. Insert the connector (6) into the receptacle on the generator. Follow the instructions in the generator user's guide to complete the setup procedure.

During Surgery**Tissue Manipulation and Dissection**

The instrument can be used to manipulate and dissect tissue with the jaws either open or closed.

Warning

Avoid placing fingers between the lever and the handle, or between the lever and the trigger, or in the jaws. Injury to the user may result.

Use caution when handling the instrument between uses to avoid accidental activation of the LigaSure system. Do not place the instrument on the patient or drapes when not in use.

Keep the cord free from the jaw and latch area of the instrument.

Warning

Fire Hazard— Do not place instruments near or in contact with flammable materials (such as gauze, surgical drapes, or flammable gases). 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.

For minimally invasive procedures, be alert to these potential hazards:

- Do not use hybrid trocars that are comprised of both metal and plastic components. Capacitive coupling of RF current may cause unintended burns.
- Use the appropriately sized trocar to allow for easy insertion and extraction of the instrument.
- Carefully insert and withdraw the instrument through the cannula to avoid damage to the device and/or injury to the patient.
- Close jaws using device lever before insertion/extraction in the trocar.

Rotating the Instrument Jaws**Notice**

Do not turn the rotation wheel (3) when the lever (8) is latched. Product damage may occur.

Turn the rotation wheel on the instrument until the jaws are in the required position.

Sealing Vessels and Tissue Bundles

1. Open the jaws by pushing forward on the lever.
2. Grasp the intended vessel and/or tissue in the center of the jaws.

Warning

Do not use this instrument on vessels larger than 7 mm in diameter.

If the instrument shaft is visibly bent, discard and replace the instrument. A bent shaft may prevent the instrument from sealing or cutting properly.

Do not place the vessel and/or tissue in the jaw hinge. Place the vessel and/or tissue in the center of the jaws.

Warning

Conductive fluids (e.g., blood or saline) in direct contact with or in close proximity to the instrument may carry electrical current or heat, which may cause unintended burns to the patient. Aspirate fluid from around the instrument jaws before activating the instrument.

Keep the external surface of the instrument jaws away from adjacent tissue while activating the LigaSure system or unintended injury may result.

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

Eliminate tension on the tissue when sealing and cutting to ensure proper function.

Use caution when grasping, manipulating, sealing, and dividing large tissue bundles.

Do not bend instrument shaft (2).

Do not attempt to seal or cut over clips or staples as incomplete seals will be formed. Contact between an active electrode and any metal objects may result in alternate site burns or incomplete seals.

The surfaces of the jaws may remain hot enough to cause burns after the RF current is deactivated.

Inadvertent activation or movement of the activated instrument outside of the field of vision may result in injury to the patient.

Do not activate the LigaSure system in an open-circuit condition. Activate the system only when the instrument is in direct contact with the target tissue to lessen the possibility of unintended burns.

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

3. Squeeze the lever until it latches in place.

Precaution

Do not activate the LigaSure system until the lever has been latched. Activating the system before latching may result in improper sealing and may increase thermal spread to tissue outside of the surgical site.

Do not overfill the jaws of the instrument with tissue, as this may reduce device performance.

Use caution during surgical procedures in which patients exhibit certain types of vascular pathology (atherosclerosis, aneurysmal vessels, etc.). For best results, apply the seal to unaffected vasculature.

Keep the instrument jaws (1) clean. Build-up of eschar may reduce the seal and/or cutting effectiveness. Wipe jaw surfaces and edges with a wet gauze pad as needed.

4. Relax the hand on the lever once latched. The device will maintain the latched position.

Notice

Do not apply additional hand force to the lever during sealing to ensure proper function.

5. The LigaSure system can be activated by either of the following two methods:
 - Press and hold the activation button (5) on the back of the instrument.

or

- By using an appropriate footswitch associated with the generator.

Refer to the generator user's guide for footswitch instructions.

Note: If both the activation button and footswitch pedal are activated during the same seal cycle, the vessel sealing system delivers energy from the activation source it detects first.

A continuous tone sounds to indicate the activation of RF energy. When the activation cycle is complete, a two-pulsed Seal-Cycle-Complete tone sounds and RF output ceases.

A tone with multiple pulses indicates that the seal cycle was not completed. Refer to the Troubleshooting section on page 6 for possible causes and corrective actions. Do not cut tissue until you have verified that there is an adequate seal.

Notice

Keep the activation button dry and clean.

6. Release the activation button on the instrument or the footswitch pedal when the seal cycle is complete.
7. To seal adjacent tissue, overlap the edge of the existing seal. The second seal should be distal to the first seal to increase seal margin.

Cutting Tissue**Warning**

Prior to cutting the seal, inspect the vessel or tissue to ensure proper sealing.

Energy-based devices, such as ES pencils or ultrasonic scalpels that are associated with thermal spread, should not be used to transect seals.

Notice

Do not engage the cutting mechanism over clips, staples, or other metal objects as damage to the cutter may occur.

1. To engage the cutting mechanism, pull the cutting trigger (9) completely back toward the body of the instrument.

Troubleshooting**Alert Situations**

When an alert condition occurs, energy delivery stops. After the alert condition has been corrected, energy delivery will be immediately available.

Troubleshooting Information

The following is a list of troubleshooting suggestions for situations encountered when using the instrument with compatible (vessel) vessel sealing generators. For details on specific situations, refer to the corresponding generator user's guide or the generator quick reference guide.

Alert Situations	When an alert condition occurs, energy delivery stops, the generator produces a sequence of pulsed tones, and an alert will be displayed on the generator. Do Not Cut the Vessel. The user should inspect the seal site and instrument before proceeding. After the alert condition has been corrected, energy delivery will be immediately available.
Troubleshooting Steps	1) Release the footswitch pedal or activation button, if still engaged. 2) Open the instrument jaws and inspect for a successful seal. 3) Follow the suggested corrective actions on the generator screen, the generator quick reference card, or in the generator user's guide. 4) If possible, reposition the instrument and regrip tissue in a location that overlaps the previous seal, then reactivate the seal cycle.

Important

If the cutting trigger does not automatically return to position, unlatch and open the lever to manually return the cutting trigger.

2. Open the jaws by squeezing the lever until it unlocks, then push it completely forward.

Warning

If the lever cannot be unlatched following use, open the device by forcing the lever forward from the handle. The device will no longer function properly and must be discarded.

Cleaning the Instrument during Use**Warning**

Inspect the instrument jaws prior to cleaning to ensure the blade is not deployed.

Do not activate the instrument or cutting trigger while cleaning the jaws. Injury to operating room personnel may result.

Wipe jaw surfaces and edges with a wet gauze pad as needed.

Notice

Do not attempt to clean the instrument jaws by activating the instrument on wet gauze. Product damage may occur.

Do not clean the instrument jaws with a scratch pad or other abrasives.

Troubleshooting Information

Too little tissue between the jaws – The user is grasping thin tissue or not enough tissue; open the jaws and confirm that a sufficient amount of tissue is inside the jaws. If necessary, increase the thickness of tissue that is grasped and reactivate the seal cycle.

Too much tissue between the jaws – The user is grasping too much tissue; open the jaws, reduce the amount of tissue that is grasped, and reactivate the seal cycle.

Activating on a metal object – Avoid grasping objects, such as staples, clips, or encapsulated sutures in the jaws of the instrument.

Reasons for Alert

Dirty jaws – Use a wet gauze pad to clean surfaces and edges of instrument jaws.

Excess Fluids in the Surgical Field – Minimize or remove excess fluids from around the instrument jaws.

Activation switch released before seal complete tone – The footswitch or activation button was released before the seal cycle was complete.

Maximum seal cycle time has been reached – The system needs more time and energy to complete the seal cycle.

After Surgery

Discard the instrument after use according to hospital policy for biohazards and sharps. **Do not resterilize.**

Pre-Clinical Study**Notice**

There is no animal data qualified to predict the effectiveness of this device in sealing vessels containing atherosclerotic plaque.

Clearance of the device in the United States was not based on human clinical testing; instead, performance of the device was established in a chronic in vivo porcine model. The results showed that no animals studied experienced any hemostatic complications related to the device during the 21-day survival period. The evaluation was performed on a variety of tissue types and vessels, up to and including 7 mm, to demonstrate effective sealing.

Vessel Type	Tissue/Vessel Name	Size Range
A/V Bundle	Omentum	<1.0 mm bundles
	Gastrosplenic	4.0 – 4.5 mm arteries within bundles
	Ovarian Pedicle	Bundles up to 5.0 mm
	Broad Ligament	Bundles up to 4.0 mm
Isolated Vessel (Artery, Vein)	Short Gastric	4.5 – 7.0 mm bundles
	Renal	4.5 mm – 7.0 mm
	Splenic	5.5 mm – 7.0 mm