

Reprocessed by



Sustainability Solutions

Instructions for Use Reprocessed LigaSure Impact™ Curved, Large Jaw, Open Sealer/Dividers

Reprocessed Device for Single Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

- **STERILE**
- **NOT MADE WITH NATURAL RUBBER LATEX**

Explanation of Icons



Sterilized by Ethylene Oxide Gas



Date of Reprocessing



Use by Date



Do Not Reuse



See Instructions For Use

LF4318

Compatible with:

FORCETRIAD SW v3.5 – v3.6

VLFT10GEN SW v1.1 – v1.1.5.4

NOTE: Devices with a Valleylab Plug are NOT compatible with VLFT10GEN SW v1.1.5.4 or higher

Reprocessed LigaSure Impact™ Curved, Large Jaw, Open Sealer / Dividers

Device Description

The Reprocessed LigaSure Impact™ Curved, Large Jaw, Open Sealer / Divider (LF4318) is a hand-held bipolar electro-surgical instrument designed for use with Covidien electro-surgical 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.

The instrument has a shaft diameter of 13.5 mm (square), shaft length of 18 cm, and a jaw length of 36 mm. The following controls are located on the instrument handle:

- A lever for opening and closing the instrument jaws. The mechanism incorporates a latch to hold the jaws in the closed position during vessel sealing and cutting.
- An activation button for generator power to initiate vessel sealing.
- A trigger for actuating the cutter.
- A knob to rotate the instrument jaws.

All controls can be operated with either the right or left hand. Vessel sealing can be initiated using the activation button or utilizing a footswitch connected to the generator.

Maximum rated voltage: 288 V_{peak}

Indications for Use

The Reprocessed LigaSure Impact™ Curved, Large Jaw, Open Sealer / Divider (LF4318) is a dedicated bipolar electro-surgical instrument intended for use in open surgical procedures where ligation and division of vessels is desired. The LF4318 is intended to be used with the Covidien electro-surgical generators that include vessel sealing capability to cut and seal vessels, and to cut, grasp, and dissect tissue during surgery. The indications for use include open procedures (general, urologic, vascular, thoracic, and gynecological) where ligation and division of vessels is performed. These procedures include vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The LF4318 can be used on vessels (arteries, veins, pulmonary vasculature, and lymph) up to and including 7 mm and tissue bundles.

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.



Defibrillation-proof type CF applied part

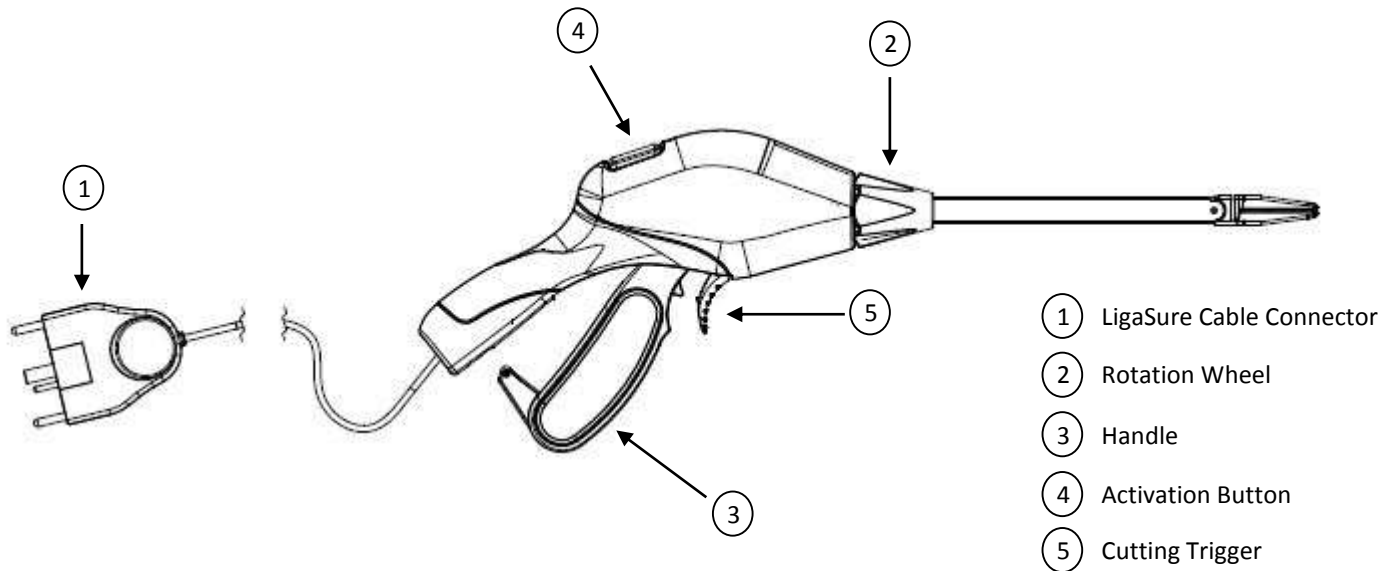
Contraindications for Use

None

Warnings

- The LF4318 instrument is intended for use ONLY with the 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 caution during surgical cases in which patients exhibit certain types of vascular pathology (atherosclerosis, aneurysmal vessels, etc.). For best results, apply the seal to unaffected vasculature.
- Do not use this instrument on vessels in excess of 7 mm in diameter.
- These instruments are only intended for use by individuals with adequate training and familiarity with the specific procedure being undertaken. Use of this equipment without such training may result in serious unintended patient injury. For further information about techniques, complications and hazards, consult the medical literature.
- Package is provided sterile by method of ethylene oxide gas and is for single patient use only. Do not use if there is any evidence of damage to the package.

Reprocessed LigaSure Impact™ Curved, Large Jaw, Open Sealer / Dividers



Directions for Use

1. Before beginning the procedure, verify overall compatibility of all instruments and accessories.
2. Inspect packaging before opening. The contents of the package are sterile if the package has not been compromised. Do not use the instrument if the sterility has been compromised. If the package is damaged or if it was opened and the instrument not used, return the instrument and the package to Stryker.
3. Do not attempt to resterilize. Stryker will not accept instruments for reprocessing that have been reprocessed and sterilized by other facilities.
4. Remove the instrument from the package by firmly pulling on the handle, taking care not to pull on the instrument's jaws or connector cable. Place it in a sterile work area using aseptic technique.
5. Inspect the instrument for overall condition and physical integrity. Do not use the instrument if any damage is noted. Return the instrument and packaging to Stryker if it is not in acceptable condition for the procedure.
6. Follow a suitable surgery protocol.
7. Instrument is intended for use during single patient procedure.

Set Up

Warning

- **Electrical Shock Hazard** – Do not connect wet accessories to the LigaSure system.
- Confirm proper energy platform settings before proceeding with surgery.
- 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.
- Position instrument cords to avoid contact with the patient or other leads. Do not wrap cords around metal objects. This may induce currents that can lead to shocks, fires, or injury to the patient or surgical team.
- Ensure all connections to the energy platform and all instruments and accessories are secure before using. Improper connection may result in arcs, sparks, accessory malfunction, or unintended surgical effects.

1. Insert the connector into the receptacle on the generator. Follow the instructions in the generator user's guide to complete the setup procedure.

LigaSure Function During Surgery

Warning

- **Fire Hazard** – 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

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a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

- Use the system with caution in the presence of internal or external pacemakers. Interference produced by the electrosurgical equipment can cause a pacemaker to enter an asynchronous mode or block the pacemaker effect entirely. Consult the pacemaker manufacturer or hospital cardiology department for further information when use is planned in patients with cardiac pacemakers.
- The jaws may remain hot enough to cause burns after the RF current is deactivated. 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.
- Place the vessel or tissue in the center of the jaws. To avoid incomplete sealing, do not grasp tissue beyond the electrode surface; do not place tissue in the jaw hinge.
- Contact between an 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 disposition.
- Conductive fluids (e.g., blood or saline) in direct contact with or in close proximity to the instrument may carry electrical current or heat. This may cause unintended burns to the patient. Remove fluid from around the instrument jaws before activation of the instrument.
- Always keep the external surface of the instrument jaws away from adjacent tissue while activating the instrument.
- During a seal cycle, energy is applied to the area between the instrument jaws. This energy may cause fluid 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.
- Do not activate RF energy until the handle has been properly latched. Activating the device before this is done may result in improper sealing and may increase thermal spread to tissue outside the surgical site.
- Do not activate the instrument while in contact with or near other instruments, including cannulas. Localized burns to the patient or physician may occur.
- Keep the cord free from the jaw and latch area of the instrument.
- Eliminate tension on the tissue while sealing and cutting to ensure proper function.
- Do not attempt to seal over clips or staples as this may result in an incomplete seal.
- If the seal-cycle complete tone has not sounded, an optimal seal may not have been reached. Reactivate the RF energy until a seal-complete tone is heard.

Caution

- Pediatric applications and/or procedures performed on small anatomic structures may require reduced power settings. The higher the current flow and the longer the current is applied, the greater the possibility of unintended thermal damage to tissue, especially during use on small appendages.
- Activate the instrument ONLY when ready to deliver electrosurgical current and when the active tip is in view.

Tissue Manipulation and Dissection

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

Rotating the Instrument Jaws

Notice – Do not turn the rotation wheel when the handle is latched. Product damage may occur.

Turn the gray rotation wheel on the handpiece to adjust the jaw position as needed.

Sealing Vessels and Tissue Bundles

1. Open the jaws by pushing forward the white, movable handle.
2. Grasp the intended vessel and/or tissue in the center of the jaws.
3. Close the handle until it clicks and latches in place.
4. Activate the instrument by either of the following methods:
 - Press and hold the purple activation button on the back of the instrument.
 - By using an appropriate footswitch associated with the generator.

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

Reprocessed LigaSure Impact™ Curved, Large Jaw, Open Sealer / Dividers

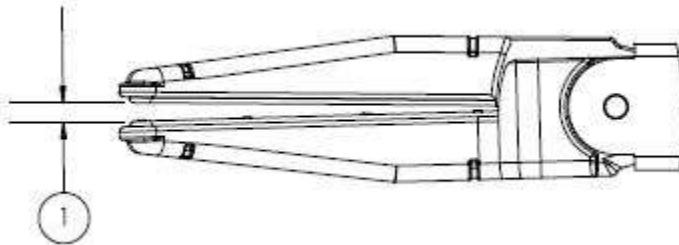
A continuous tone sounds to indicate that the vessel or tissue is being sealed. When the activation cycle is complete, a double end tone sounds and the energy platform discontinues RF output.

5. Release the purple activation button on the instrument, or the footswitch pedal when the seal cycle is complete.
6. 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. Failure to overlap seals when a second seal is desired may compromise seal integrity.

Cutting Tissue

Warning

Do not overfill the jaws of the instrument with tissue. This may damage the cutting mechanism or cause the blade to deploy outside of its guiding features, possibly resulting in difficulty opening the jaws or unintended injury to the user or patient.



① < 2 mm – Confirm that the jaws are in the closed position prior to activating the cutter.

Caution

Energy-based devices, such as ESU 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 sutures, clips, staples, or other metal objects as damage to the cutter may occur.

1. Prior to cutting the seal, the surgeon can inspect the vessel or tissue to ensure proper sealing: compressed, translucent or opaque seal with signs of desiccation and visible hemostasis. If not properly sealed, repeat seal cycle, adjusting the settings if needed.
2. To engage the cutting mechanism, pull the cutting trigger completely back toward the body of the instrument. The instrument blade transects the seal an average of 2 mm from the distal end of the seal plate.
3. Open the jaws by squeezing the handle until it unlocks, then push the handle completely forward.

Cleaning the Instrument During Use

Warning

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

Important: Keep the instrument jaws clean. Build-up of eschar may reduce sealing and/or cutting effectiveness. Wipe jaw surfaces and edges with a sterile, water- or saline-soaked gauze pad as needed. Do not clean instrument jaws with a scratch pad.

Troubleshooting

Reprocessed LigaSure Impact™ Curved, Large Jaw, Open Sealer / Dividers

Alert Situations

- 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 tone with multiple pulses indicates that the seal cycle was not completed. Do not cut tissue until you have verified that there is an adequate seal.
- When an alert condition occurs, energy delivery will be terminated, resulting in an incomplete seal. After the alert condition has been corrected, the device can be reactivated.

Check Instrument/Seal Cycle Incomplete

A Check Instrument/Seal Cycle Incomplete alert condition produces a sequence of pulsed tones and an alert will be displayed on the generator. The user should inspect the seal site and instrument before proceeding. If the Check Instrument/Seal Cycle Incomplete alert appears:

1. Release the footswitch pedal or activation button.
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, regrasp tissue in another location, then reactivate the seal cycle.

Regrasp thicker tissue – For thin tissue, open the jaws and confirm that a sufficient amount of tissue is inside the jaws. If necessary, increase the amount of tissue and repeat the procedure.

Check for clips / Regrasp tissue – Avoid grasping objects such as staples, clips, or encapsulated sutures in the jaws of the instrument.

Clean electrode tips – Use a sterile, water- or saline-soaked gauze pad to clean surfaces and edges of instrument jaws.

Remove excess fluids – Minimize or remove excess fluids that pool around the instrument tip.

Reactivate/Seal Cycle Incomplete Alert

A Reactivate/Seal Cycle Incomplete alert condition produces a sequence of pulsed tones and an alert will be displayed on the generator.

If the Reactivate/Seal Cycle Incomplete alert appears, the user should:

1. Release the footswitch pedal or activation button.
2. Reactivate the seal cycle without removing or repositioning the jaws from their original position.

Reasons:

- Maximum seal cycle time has been reached. The system needs more time and energy to complete the seal.
- Seal cycle/endpoint was interrupted before the cycle was complete. The footswitch or activation button was released before the seal cycle was complete.

After Surgery

- Discard the LF4318 instrument after use according to hospital policy for biohazards and sharps.

Pre-Clinical Study

Notice

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

Product 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. In addition, there was no evidence of thermal injury or other device-related damage to adjacent tissue. A variety of tissue types and vessels were evaluated to demonstrate effective sealing in arteries and veins up to and including 7mm.

The United States clearance of this device was not based on human clinical testing.

Reprocessed LigaSure Impact™ Curved, Large Jaw, Open Sealer / Dividers

Vessel Type	Vessel Identification	Vessel Size Range
A/V Bundle	Splenic Mesentery	Bundles up to 2 mm
	Gastrosplenic	4 mm - 6 mm
	Short Gastric	3 mm - 7 mm
	Ovarian Pedicle	Bundles up to 7 mm
Artery	Splenic	4 mm - 6 mm
	Renal	Arteries up to 7 mm
Vein	Splenic	4 mm - 5 mm
	Renal	4 mm - 6 mm

Transport and Storage Conditions

- An ambient temperature range of -18°C to 60°C.
- Do not expose to relative humidity above 90%.

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Warranty

Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE PRODUCT.

Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

General Warranty Terms Applicable to All Products

TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL STRYKER'S LIABILITY ARISING IN CONNECTION WITH THE SALE OF THE PRODUCT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, MISREPRESENTATION, FRAUD, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY OF LAW) EXCEED THE PURCHASE PRICE, CURRENT MARKET VALUE OR RESIDUAL VALUE OF THE PRODUCTS, WHICHEVER IS LESS. STRYKER SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

Reprocessed LigaSure Impact™ Curved, Large Jaw, Open Sealer / Dividers

The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product then is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

Covidien™ is a registered trademark of Covidien AG.

ForceTriad™, LigaSure™, and LigaSure Impact™ are trademarks of a Covidien company.

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