Reprocessed by

stryker®

Sustainability Solutions

Instructions for Use
Reprocessed LigaSure Impact without Nano-coating 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 Symbols

STERILE EO	Sterilized by Ethylene Oxide Gas
	Date of Reprocessing
	Use by Date
	Do Not Reuse
	See Instructions For Use

LF4418	**Compatible with**: FORCETRIAD SW v3.6 – v4.0 VLFT10GEN SW v1.1 – v2.0.1.13

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Reprocessed LigaSure Impact™ without Nano-coating Large Jaw, Open Sealer/Dividers Description

The Reprocessed LF4418 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 is lower than required, contact Covidien about software updates.

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

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.

Maximum rated voltage: 288 V_{peak}

Indications for Use

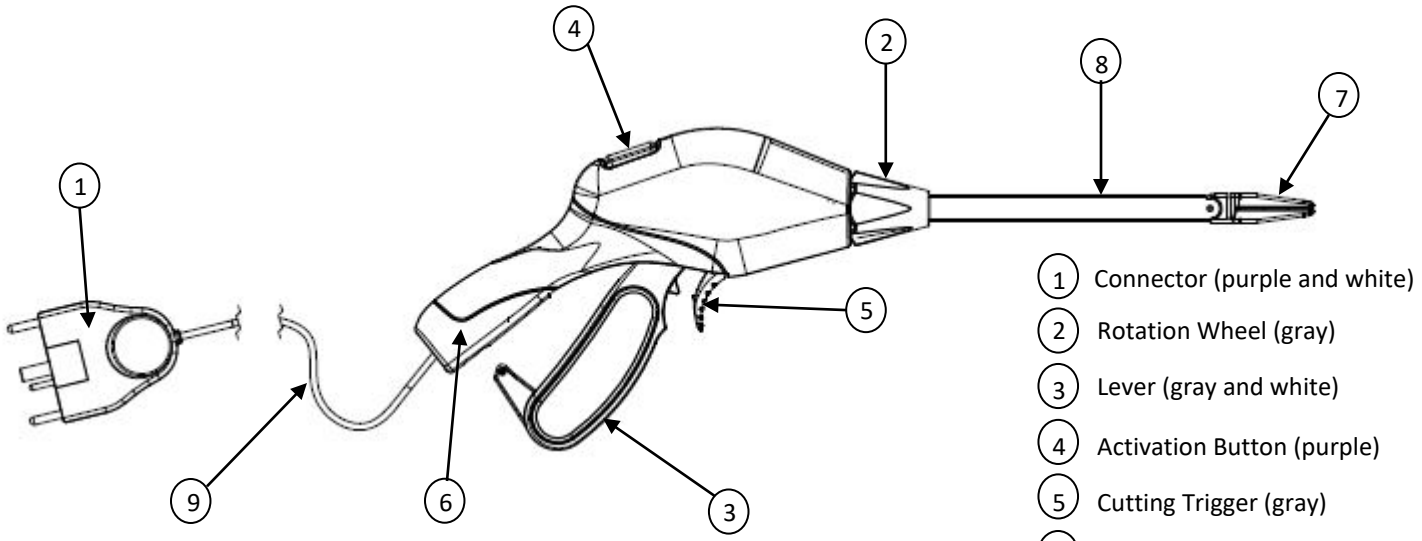
The Reprocessed LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The Reprocessed LigaSure Sealer/Divider can be used on vessels (arteries, veins, pulmonary arteries, pulmonary 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.


Defibrillation-proof type CF applied part

General Warnings

- The nano-coating featured on the original device is not present on this product.
- 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.
- The safe and effect 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.
- Contact between an active instrument electrode and any metal object (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.
- 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.



Directions for Use

Precaution

- 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.
- Pediatric applications and/or procedures performed on small anatomic structures may require reduce 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.

Set Up

Warning

- **Electrical Shock Hazard** - Do not connect wet accessories to the generator.
- 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.
- Examine all LigaSure system and instrument connections before using. Improper connections may result in arcing, sparks, accessory malfunction, or unintended surgical effects.
- Do not use in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N_2O) 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.
- 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.
- 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.

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 (6). Do not pull on the instrument jaws (7) or cable (9).

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

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 a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.
- 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.
- The surface of the jaws may remain hot enough to cause burns after the RF current is deactivated.
- 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.
- Do not use this instrument on vessels in excess of 7 mm in diameter.
- 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 tissue 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 the LigaSure system 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, as 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 incomplete seals/damage to the cutting blade will occur. Contact between an active electrode and any metal objects may result in alternate site burns or incomplete seals.
- Use caution during surgical cases in which patients exhibit incompressible tissue. There may be limitations associated with effective use of the device in these situations.
- Although the jaws of the instrument will accommodate tissue greater than 15 mm thick, exceeding the tissue thickness limit of 15 mm could result in compromised seals.

Precaution

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 (2) when the lever (3) 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

Warning

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.

Precaution

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

1. Open the jaws by pushing forward on the lever.

2. Grasp the intended vessel and/or tissue in the center of the jaws.
3. Squeeze the lever until it latches in place.
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. Activate the instrument by either of the following methods:
   - Press and hold the activation button (4) 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.
     Note: If both the activation button and footswitch pedal are activated during the same seal cycle, the generator 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.

Notice – The surgeon may inspect the seal before cutting the vessel or tissue. After inspecting the seal, the surgeon should create a second seal adjacent to the first seal before cutting, as described below.

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.

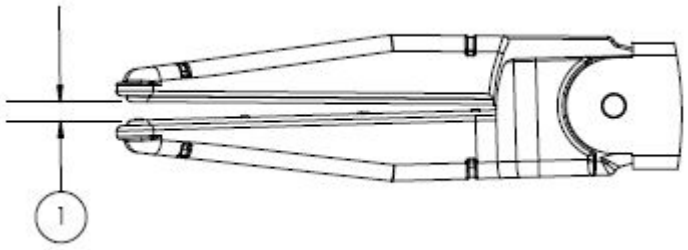
Notice – Keep the activation button dry and clean.

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. 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 difficultly opening the jaws or unintended injury to the user or patient.
- Energy-based devices, such as ESU pencils or ultrasonic scalpels, that are associated with thermal spread should not be used to transect seals.



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

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

1. To engage the cutting mechanism, pull the cutting trigger (5) 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.
2. Open the jaws by squeezing the handle until it unlocks, then push the handle completely forward.

Cleaning the Instrument During Use

Warning

- Inspect the instrument jaws prior to cleaning to ensure blade is not deployed.
- Do not activate the instrument or the 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.
- Remove any embedded tissue from blade track and jaw hinge area.
- Do not clean the instrument jaws with a scratch pad or other abrasives.

Troubleshooting

The following is a list of troubleshooting suggestions for situations encountered when using the instrument with compatible Covidien 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. 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 Covidien 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 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 regrasp tissue in a location that overlaps the previous seal, then reactivate the seal cycle.
Reason for alert	**Too little tissue between the jaws** – The user is grasping thin tissue or not enough tissue; open the jaws and confirm that 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. **Dirt jaws** – Use a wet gauze pad to clean surfaces and edges of instrument jaws. **Excess Fluids in Surgical Field** – Minimize or remove excess fluids from around the instrument jaws. **Activation switch released before seal completes 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 facility's 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.

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. 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.

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 below 15% or above 90%.

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.

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.

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