

Reprocessed by



Sustainability Solutions

Instructions for Use Reprocessed LigaSure™ Blunt Tip Laparoscopic 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

 Sterilized by Ethylene Oxide Gas

 Date of Reprocessing

 Use by Date

 Do Not Reuse

 See Instructions For Use

Reprocessed LigaSure™ Blunt Tip Laparoscopic Sealer/Dividers

Device Description

The Reprocessed LigaSure™ Blunt Tip Laparoscopic Sealer/Divider (LF1537) is a bipolar electro-surgical instrument for use in performing laparoscopic surgical procedures using the ForceTriad™ Energy Platform.

The outer diameter of the instrument shaft is 5 mm, with a working length of 37 cm. The following controls are located on the instrument handle:

- A lever (handle) 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. The cutter can only be actuated when the jaws are closed and latched.
- A knob (rotation wheel) 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. The instrument attaches to the generator via a ten-foot cable with a Smart™ connector that identifies the instrument type to the generator.

The Reprocessed LigaSure™ Blunt Tip Laparoscopic Sealer/Divider is an instrument that works exclusively with the Covidien™ ForceTriad™ energy platform. The LF1537 is compatible only with ForceTriad system software version 3.10 or higher.

The software version should appear on the center display screen when you turn on the ForceTriad™ energy platform. Reprocessed LigaSure™ Blunt Tip Laparoscopic Sealer/Dividers are only compatible with the ForceTriad™ energy platform, which supplies a maximum voltage of 288 Volts (peak).



Defibrillation-proof type CF applied part

Indications for Use

The Reprocessed LigaSure™ Blunt Tip Laparoscopic Sealer/Divider is a bipolar electro-surgical instrument intended for use with the ForceTriad™ Energy Platform in general and gynecologic laparoscopic surgical procedures where ligation and division of vessels and lymph is desired. The instrument creates a seal by application of RF electro-surgical energy to vascular structures (vessels and lymph) interposed between the jaws of the instrument. A blade within the instrument is surgeon actuated to divide tissue.

Indications for use include general laparoscopic procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic procedures where ligation and division of vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

The Reprocessed LigaSure™ Blunt Tip Laparoscopic Sealer/Divider can be used on vessels and lymphatics up to and including 7mm and tissue bundles as large as will fit in the jaws of the instrument. The device can also be used to seal pulmonary vasculature but only when used with the ForceTriad™ Energy Platform.

Contraindications for Use

None

Warnings

- The Reprocessed LigaSure Blunt Tip Laparoscopic Sealer/Dividers are intended for use ONLY with the ForceTriad energy platform. Injury to the patient or surgical team, or damage to the instrument and undesirable tissue effects could occur when this instrument is used with other Covidien generators or with generators produced by other manufacturers.
- 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.
- These instruments are only intended for use by individuals with adequate training and familiarity with the specific

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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.

- The LigaSure system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.
- Use caution during surgical cases in which patients exhibit certain types of vascular pathology, such as atherosclerosis, aneurysmal vessels, etc. For best results, apply the seal to unaffected vasculature.
- Do not use this device on vessels in excess of 7mm in diameter.
- Before starting the procedure, confirm proper energy platform settings. The default setting is 2 green bars.
- Place the vessel and/or tissue in the center of the jaws. Do not place the vessel and/or tissue in the jaw hinge.
- Contact between an active instrument electrode and any metal object, such as 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.
- Refrain from placing fingers between the handle and the handset, or between the handle and the trigger, or in the jaws as user injury may occur.
- **Electrical Shock Hazard** – Do not connect wet accessories to the LigaSure system.
- **Fire Hazard** – Instruments that are activated or hot from use may cause a fire. Do not place instruments near or in contact with flammable materials such as gauze, surgical drapes or flammable gases. When not in use, place instruments in a clean, dry, highly visible area not in contact with the patient. Unintended contact with the patient may result in burns.
- Be alert to these potential hazards for laparoscopic procedures:
 - Do not use hybrid trocars that are comprised of both metal and plastic components. Unintended burns may result from capacitive coupling of RF current.
 - Use the appropriate sized trocar to allow for easy insertion and extraction of the instrument.
 - Close the jaws using the device handle before insertion/extraction in the trocar. To avoid possible damage to the instrument and/or injury to the patient, carefully insert and withdraw the instruments from cannulas of the trocars.
- During a seal cycle, energy is applied to the area between the instrument jaws and 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. In anticipation of this possibility, care should be taken in surgical procedures occurring in confined spaces.
- Do not activate the LigaSure system until the instrument has been latched. Activating the system prior to latching the instrument may result in improper sealing and may increase thermal spread to tissue outside the surgical site.
- Exercise caution when handling the instrument between uses to avoid accidental activation. Place instrument off of the patient and drapes when not in use.
- Conductive fluids, such as 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. Before activating the instrument, remove fluid from around the instrument jaws.
- While activating the instrument, keep the external surface of the instrument jaws away from adjacent tissue or unintended injury may result.
- Do not activate the LigaSure system in an open circuit condition. Only activate the system when the instrument is in direct contact with the target tissue to lessen the possibility of unintended burns.
- Prior to usage, examine the instrument and cords for breaks, cracks, nicks, or other damage. Failure to observe this caution may result in injury or electrical shock to the patient or surgical team or cause damage to the instrument. Do not use if damaged.
- 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.
- Keep the cord free from the jaw and latch area of the instrument.
- 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 the field of vision may result in injury to the patient.
- Before using, inspect all LigaSure system and instrument connections. Improper connection may result in arcs, sparks, accessory malfunction, or unintended surgical effects.
- Use caution when using the system in the presence of internal or external pacemakers. Interference produced by the ForceTriad energy platform generator can cause a pacemaker to enter an asynchronous mode or can block the pacemaker effect entirely. For further information, consult the pacemaker manufacturer or hospital cardiology department when use is planned in patients with cardiac pacemakers.

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- When the instrument jaws are in contact with or near other instruments (including metal cannulas) do not activate the instrument, as localized burns to the patient or physician may occur.
- **WARNING:** No modification of this instrument is allowed.
- In case the instrument is accidentally dropped on the floor, turn off the generator and unplug the instrument prior to discarding.

Adverse Reactions

None

Directions for Use

- The package label is detachable and may be affixed to the medical record of the patient.
- Verify compatibility of all instruments and accessories before beginning the procedure.
- Inspect the package 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 packaging to Stryker.
- Do not attempt to resterilize.
- Remove the instrument from the package by firmly pulling on the handset taking care to not pull on the instrument's jaws or cable. Place the instrument in a sterile work area using aseptic technique.
- 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 surgery.

Set Up

1. Insert the instrument's Smart Connector into the one of the LigaSure receptacles under the right-most LigaSure touchscreen on the ForceTriad energy platform front panel.
2. The energy platform recognizes the instrument type by reading the instrument's Smart Connector and sets the intensity setting to 2 bars in the display.
3. If you have entered the settings into the LigaSure touchscreen prior to connecting the instrument, these settings will reset to 2 bars. This setting may need to be adjusted during the procedure. The bar setting are used as follows:
 - **1 Green Bar** – used with isolated small tissue bundles.
 - **2 Green Bars** – used with average tissue bundles.
 - **3 Green Bars** – used with larger tissue bundles. This setting will increase fusion times.

During Surgery

Tissue Manipulation and Dissection

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

Rotating the Instrument Jaws

Do not turn the rotation wheel when the handle is latched. Product damage may occur. Turn the gray 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 handle.
2. Grasp the intended vessel and/or tissue in the center of the jaws.

Warning

- Use caution when grasping, manipulating, sealing, and dividing large tissue bundles.
 - Do not bend instrument shaft.
 - To ensure proper function, eliminate tension on the tissue while sealing and cutting.
 - Do not attempt to seal over clips or staples as incomplete seals may be formed.
3. Squeeze the handle until it latches in place.
 4. Relax the hand on the handle once latched. The device will maintain the latched position.
 - Do not apply additional hand force to the handle during sealing to ensure proper function.

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- The instrument can be activated by either of the following two methods:
 - Press and hold the purple activation button on the back of the instrument.
 - Or depress and hold the corresponding round purple or orange footswitch pedal on the ForceTriad energy platform.
 - A continuous tone sounds to indicate that the vessel or tissue is being sealed. When the seal cycle is complete a two-pulsed end tone sounds and RF output ceases.**
- When the seal cycle is complete, release the activation button on the instrument or the footswitch pedal.
 - Keep the activation button dry and clean.
- Overlap the edge of the existing seal to seal adjacent tissue. The second seal should be distal to the first seal to increase seal margin.

Cutting Tissue

Warning

- Energy based devices that are associated with thermal spread, such as ES pencils or ultrasonic scalpels, should not be used to transect seals.
- If the handle cannot be unlatched following use, open the device by forcing the handle forward. The device will no longer function properly and must be discarded.

Note

- The knife will not engage if the instrument shaft is bent. Discard and replace the bent instrument.
 - Do not engage the cutting mechanism over metal objects, such as clips and staples, as damage to the cutter may occur.
 - Do not leave the handle in the latched position when the instrument is not in use.
- Prior to cutting the seal, inspect the vessel or tissue to ensure proper sealing.
 - Pull the cutting trigger completely back towards the body of the instrument to engage the cutting mechanism.
 - If the cutting trigger does not automatically return to position, unlatch and open the handle to manually return the cutting trigger.
 - Open the jaws by squeezing the handle until it unlocks, then push it completely forward.

Cleaning the Instrument During Use

Warning

- While cleaning the jaws, do not activate the instrument or the cutting trigger as user injury may result.

Note

- Keep the instrument jaws clean. Build-up of eschar may reduce sealing and/or cutting effectiveness. Wipe jaw surfaces and edges with a wet gauze pad as needed.
- Do not clean the instrument jaws with a scratch pad or other abrasives.

Troubleshooting

Note:

- If both the activation button and footswitch pedal are activated during the same seal cycle, the ForceTriad delivers energy from the activation source it detects first.
- A four-pulsed tone will sound when an alert condition occurs, and the LigaSure touchscreen on the ForceTriad will display an alert message that instructs the user on the corrective actions to take.
- When an alert condition occurs, energy delivery will be terminated, but will be available immediately after the alert condition has been corrected.

Check Instrument

Should an alert condition and/or incomplete tissue fusion cycle alert occur, do not repeatedly activate before checking the instrument as indicated below.

If this message appears, the user should:

- Release the footswitch pedal or activation button.
- Open the instrument jaws and inspect for a successful seal.
- Follow the suggested remedies in the Check Instrument screen.

If possible, reposition the instrument and regrasp tissue in another location, then reactivate the seal cycle.

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Potential Remedies

- *Regrasp thicker 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 wet gauze pad to clean surfaces and edges of instrument jaws.
- *Remove excess fluids* – Pooled fluids around the instrument tip; aspirate excess fluids.

Endpoint Not Reached

If this message appears the user should:

- Release the activation button or the footswitch pedal.
- 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 was interrupted before the cycle was complete. The activation button or footswitch pedal was released before the seal cycle was complete.

After Surgery

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

Transport and Storage Conditions

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

Operating Conditions

- An ambient temperature range of +10°C to +40°C.

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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.

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The OM 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™ and LigaSure™ are trademarks of a Covidien company.

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