Reprocessed by

stryker

Instructions for use

Reprocessed LigaSure Curved, Small Jaw, Open Sealer/Divider

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
- Exposed to Ethylene Oxide (EO) gas

LF1212A	**Compatible with:** FORCETRIAD SW v3.6 – v4.0 VLFT10GEN SW v1.1 – v4.0.2.25

Explanation of symbols

Symbol	Rules/ Standard Reference	ISO 7000 Registration Number	Symbol Title	Description
	ISO 15223-1:2016	2501	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	ISO 15223-1:2016	2497	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1:2016	2607	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1:2016	2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1:2016	2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1:2016	1641	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1:2016	1051	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 15223-1:2016	2608	Do not resterilize	Indicates a medical device that is not to be resterilized.
	ISO 15223-1:2016	2606	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1:2016	0626	Keep dry	Indicates a medical device that needs to be protected from moisture.
	ISO 7000:2019	3010	Contains RFID tag	Indicates the presence of the RFID tag incorporated within the packaging, container, or equipment without identifying the specific air interface or data structure employed.

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Reprocessed LigaSure Curved, Small Jaw, Open Sealer/Divider description

The LF1212A 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 updates.

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 cautions.

The instrument creates a seal by application of radiofrequency (RF) electrosurgical energy to vascular structures (vessels and lymph) or tissue bundles interposed between the jaws of the instrument. A cutting blade within the instrument is surgeon-activated to divide tissue.

Maximum rated voltage: 288 V_{peak}

Not made with natural rubber latex


Do not use if package is opened or damaged

Type CF applied part

Indications for use

The Reprocessed LF1212A 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 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 in such surgical specialties as urologic, thoracic, plastic, and reconstructive. Procedure may include, but are not limited to, bowel resections, gall bladder procedures, Nissen fundoplication, and adhesiolysis.

The instrument is also indicated for open ENT procedures in adults (thyroidectomy, radical neck dissection, parotidectomy, and tonsillectomy) for ligation and division of vessels, lymphatics and tissue bundles 2-3 mm away from unintended thermally-sensitive structures such as nerves and parathyroid glands.

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.

Contraindications for use

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.

Warnings

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.

This 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.

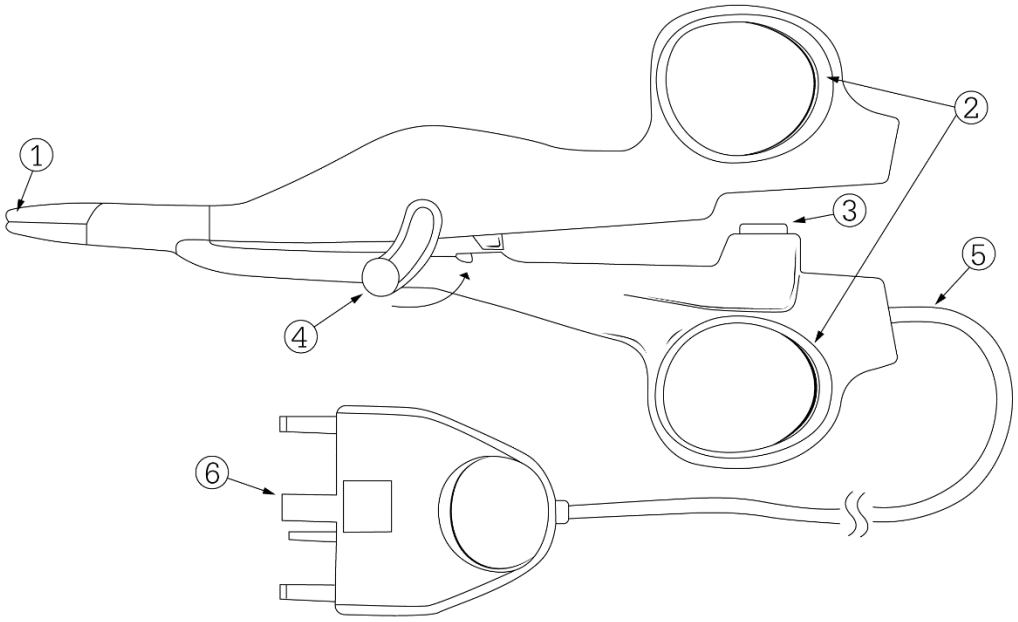
Use the system with caution in the presence of internal or external pacemakers or other implanted devices. Interference produced by electrosurgical equipment can cause a pacemaker or other device to enter an unsafe mode or permanently damage the device. Consult the device manufacturer or responsible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

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.

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.

Precautions

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.



① Jaws (gray)
② Ring handles (gray and white)
③ Hand-activation button (purple)
④ Cutting triggers (gray), one on each side (arrow shows direction for cutting)
⑤ Cable/cord
⑥ Connector (purple and white)

Procedures performed on small anatomic structures may require reduced power settings. The higher the current glow and the longer the current is applied, the greater the possibility of unintended thermal damage to tissue, especially during use on small appendages.

Adjunctive use of nerve-monitoring device is recommended during nerve-sparing procedures such as thyroidectomies, radical neck dissection and parotidectomies.

Secondary hemorrhaging after tonsillectomy is a potentially serious adverse event. According to some reports, electrosurgical devices may be associated with a small increase in the incidence of secondary post-tonsillectomy hemorrhaging.

Set-up

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.

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 (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.

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 ring handles (2). Do not pull on the instrument jaws (1) or cord (5).
2. Insert the connector (6) of the LF1212A into the receptacle on the generator. Follow the instructions in the generator user's guide to complete the setup procedure.

During Surgery

The LF1212A instrument can be used during surgery both to manipulate and dissect tissue, and to seal and cut vessels and tissue bundles. Instructs for use of the instrument during a procedure are provided in this section.

Warning

Avoid placing fingers between the jaws or ring handles. Injury to the use 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 cable free from between the jaws and ring handles of the instrument.

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.

Precaution
Do not use the LF1212A as bipolar scissors. Continual activation to separate tissue promotes eschar buildup on seal surfaces that can reduce the effectiveness of the seal, and may create a condition that compromises the jaw's insulating coating.

Tissue Manipulation and Dissection

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

Sealing Vessels and Tissue Bundles

Warning
Prior to sealing or manipulating tissue, ensure that the cutting blade is not exposed.

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

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

Do not divide tissue before the seal cycle is complete as this may result in improper sealing.

Do not pull the cutting trigger while the jaws are open as injury to the patient or surgical team may occur.

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.

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

Do not attempt to seal or cut 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.

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 or surgical team.

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.

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

Precaution
When intending only to grasp or manipulate tissue, ensure pressure to the ring handles does not cause the second click that activates energy delivery.

Keep the instrument jaws 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.

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

Hand Activation

Notice

Closing the ring handles to the second click activates or reactivates energy delivery if hand-activation is being used.

1. Ensure hand-activation is enabled on the appropriate port. Refer to the generator user's guide if needed.
2. Grasp the intended vessel and/or tissue in the center of the jaws.
3. Close the ring handles until you hear or feel two clicks. At the second click, energy is delivered.

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.

4. 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.

Footswitch Activation

A footswitch can be used instead of the hand-activation button (3). Ensure that the footswitch is connected to the footswitch receptacle that corresponds to the LF1212A instrument receptacle in use.

Warning

Activating energy delivery with a footswitch when the hand-activation button is not in the second-click position may result in improper sealing and increase thermal spread to tissue outside the surgical site. The second click of the hand-activation button indicates proper pressure is being applied to the tissue.

1. Connect the footswitch to the generator as described in the generator user's guide.
2. Ensure hand-activation is disabled on the appropriate port. Refer to the generator user's guide if needed.
3. Grasp the intended vessel and/or tissue in the center of the jaws.
4. Press and hold ring handles to the second click to ensure appropriate pressure on the grasped tissue.
5. Press and hold the footswitch pedal to activate energy.

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.

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.

Cutting Tissue

Warning

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

Notice

Failure to maintain steady pressure on the ring handles while cutting could result in inadvertent reactivation of energy.

1. To divide tissue, maintain steady pressure on the ring handles and pull the cutting trigger (4) until a hard stop is reached. Then release the cutting trigger to allow the cutting blade to retract.
2. Open the jaws to release tissue.

Cleaning the Instrument During Use

Warning

Inspect the instrument jaws prior to cleaning to ensure the cutting 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.

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.

Alert	Troubleshooting Information
Check Instrument/Seal Cycle Incomplete Alert	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, 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 regrasp tissue in another location, then reactivate the seal cycle.
Reasons for Check Instrument/Seal Cycle Incomplete Alert	**Regrasp thicker tissue** – 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 amount of tissue and reactivate the seal cycle. **Check for clips/Regrasp tissue** – Avoid grasping objects, such as staples, clips, or encapsulated sutures in the jaws of the instrument. **Remove excess fluids** – Minimize or remove excess fluids from around the instrument jaws.

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, if still engaged. 2. Reactivate the seal cycle without repositioning the instrument. 3. Follow the suggested corrective actions on the Seal Cycle Incomplete generator screen, the generator quick reference card, or in the generator user's guide,
Reason for Reactivate/Seal Cycle Incomplete Alert	**Seal cycle/endpoint interrupted before seal cycle was complete** – 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. **Inspect seal and reactivate instrument** – Follow the suggested corrective actions on the generator screen, the generator quick reference guide, or in the generator user's guide.

After Surgery

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

Pre-Clinical Studies

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 was evaluated to demonstrate effective sealing in arteries and veins up to and including 7 mm. The United States clearance of this device was not based on human clinical testing.

In Vivo Vessel Performance (Chronic)		
Vessel Type	**Tissue/Vessel Name**	**Vessel Size Range**
A/V Bundle	Gastrosplenic	6.0 mm – 7.0 mm
	Ovarian Pedicle	1.0 mm – 6.0 mm
	Short Gastric	2.0 mm – 7.0 mm
Isolated Vessel (Artery, Vein)	Renal	3.0 mm – 7.0 mm
	Splenic	5.0 mm – 7.0 mm

Standards and IEC Classifications

The Reprocessed LigaSure Curved, Small Jaw, Open Sealer/Divider meets all pertinent clauses of IEC 60601-1 Edition 3+A1;C1, IEC 60601-1-2, and IEC 60601-2-2 Edition 6.0.

If the Reprocessed LigaSure Curved, Small Jaw, Open Sealer/Divider experience loss or degradation of the essential performance described in these instructions as a result of EMC disturbances, there would be no effect to intended use.

The medical device is suitable to be used in the Professional Healthcare Facility Environment.

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.

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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