

Reprocessed by



Sustainability Solutions

Instructions for Use Reprocessed Hand Activated 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**
- **LATEX FREE**

Explanation of Icons

 Sterilized by Ethylene Oxide Gas

 Date of Reprocessing

 Use by Date

REF Product Code

 Do Not Reuse

 See Instructions For Use

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Reprocessed Hand Activated Sealer/Divider

Device Description

The reprocessed LigaSure Impact™ LF4200 (hereinafter Hand Activated Sealer/Divider) is an instrument that works exclusively with the Force Triad™ energy platform utilizing the TissueFect™ sensing technology that precisely manages energy delivery for consistent controlled tissue effects. The shaft diameter is 13.5 mm (oval), length is 18 cm and shaft rotation is 180 degrees.

Indications for Use

The Reprocessed Hand Activated Sealer/ Divider can be used during open procedures to seal vessels up to and including 7mm, lymphatics and tissue bundles. The Hand Activated Sealer/Divider can also be used to seal pulmonary vasculature but only when used with the ForceTriad™ energy platform.

Contraindications for Use

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.

Warnings

- The Hand Activated Sealer/Divider is intended for use ONLY with the Valleylab ForceTriad™ energy platform. Injury to the patient or surgical team, or damage to the instrument could occur when this instrument is used with other Valleylab generators or with generators produced by other manufacturers.
- Do not use with the Valleylab LigaSure™ vessel sealing system.
- 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 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.
- Use caution during surgical cases in which patients exhibit certain types of vascular pathology like 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.
- Place the vessel or tissue in the center of the jaws. Avoid incomplete vessel sealing by not grasping tissue beyond the electrode surface or placing it in the jaw hinge.
- Contact between an active instrument electrode and any metal object may increase current flow and can result in unintended surgical effects such as an effect at an unintended site or insufficient energy disposition.
- Do not activate the LigaSure™ system in the vessel sealing mode until the vessel sealing instrument has been applied with the proper pressure. Activating the system before this is done may result in improper seal and may increase thermal spread to tissue outside the surgical site.
- Refrain from placing fingers in the handle ratchet mechanism as user injury may occur.
- **Electrical Shock Hazard** – Do not connect wet accessories to the generator/energy platform.
- **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 or surgical drapes. When not in use, place them in a clean, dry highly visible area not in contact with the patient. Unintended contact with the patient may result in burns.
- During a seal cycle, energy is applied to the area between the instrument jaws. This energy may cause water to be converted into steam. The thermal energy of steam may cause unintended injury in close proximity to the jaws. In anticipation of this possibility, care should be taken in surgical procedures occurring in confined spaces.
- Conductive fluids like blood or saline in direct contact with or 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, always keep the external surface of the instrument jaws away from adjacent tissue.
- 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 leads. 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.
- Before using, inspect all connections to the energy platform and all instruments and accessories. Improper connection may result in arcs, sparks, accessory malfunction, or unintended surgical effects.

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- When the instrument is in contact or near other instruments (including cannulas) do not activate the instrument, as localized burns to the patient or physician may occur.

Precautions

- Energy based devices that are associated with thermal spread such as ESU pencils or ultrasonic scalpels should not be used to transect seals.
- Reduced power settings may be required for applications and/or procedures performed on small anatomic structures. The higher current flow and the longer the current is applied, the greater the possibility of unintended thermal damage to tissue, especially during the use on small appendages.
- Prior to use, examine the energy platform and accessories for defects. If connectors or insulation on the cables or accessories are damaged, do not use. .
- Only activate the instrument when the active tip is in view and ready to deliver electrosurgical current

Adverse Reactions

None.

Directions for Use

1. The package label is detachable and may be affixed to the medical record of the patient.
2. Verify compatibility of all instruments and accessories before beginning the procedure,
3. 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.
4. Do not attempt to resterilize.
5. Remove the instrument from the package and place it in a sterile work area using aseptic technique.
6. 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

7. With the bar code on the LigaSmart™ connector facing up, firmly insert it into the one of the hand activated sealer divider receptacles under the right LigaSure touchscreen on the energy platform front panel.
8. The energy platform recognizes the instrument type by reading the Instrument's Smart connector.
9. The user must select the appropriate bar setting to achieve the desired tissue effect. This setting may need to be adjusted during the procedure.
 - **1 Green Bar** – used on isolated or small tissue bundles.
 - **2 Green Bars** – used with average tissue bundles.
 - **3 Green Bars** – used on larger tissue bundles. This setting may slightly increase fusion times.

Note: The system detects the connected hand activated sealer divider instrument and sets the Intensity setting to 2 bars in the display. If you have entered settings in the LigaSure™ touch screen prior to connecting the hand activated sealer divider instrument, these settings will be reset to 2 bars.

During Surgery

Warning

- Do not activate the LigaSure™ function until the handle has been properly latched. Activating the function before this is done may result in improper sealing and may increase thermal spread to tissue outside the surgical site.
- 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.

Tissue manipulation and dissection

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

Rotating the Instrument Jaws.

10. Turn the rotation wheel on the handpiece until the jaws are in the required position. Do not turn the rotation wheel when the handle is latched. Product damage may occur. The jaws may lock in the closed position.

Sealing vessels and tissue bundles

11. Open the jaws by pushing forward on the white movable handle.
12. Grasp the intended vessel and/or tissue in the center of the jaws. To avoid incomplete vessel sealing, do not grasp tissue beyond the electrode surface; do not place tissue in the jaw hinge.

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13. Close the white movable handle until it clicks and latches in place.
14. 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.
 - Depress and hold the corresponding round purple or orange foot pedal.
 - A continuous tone sounds to indicate that the vessel or tissue is being sealed. A double end tone sounds and the energy platform discontinues RF output when the activation cycle is complete.
15. When the cycle is complete, release the activation button (purple) on the instrument or the foot pedal (orange or purple).
16. Overlap the edge of the existing seal to seal adjacent tissue.

Cutting Tissue

- Energy based devices that are associated with thermal spread such as ESU pencils or ultrasonic scalpels should not be used to transect seals.
 - Avoid overfilling the instrument jaws 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.
 - Visually confirm that the jaws have reached the closed position prior to activating the cutter. Failure to do so 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.
 - Prior to activating the cutter, confirm that the jaws are in the closed position. Spacing between jaws must be less than two millimeters.
 - Do not engage the cutting mechanism over metal objects such as sutures, clips and/or staples, as damage to the cutter may occur.
17. Prior to cutting the seal, the surgeon may inspect the vessel or tissue to ensure proper sealing.
 18. Pull the cutting trigger completely back towards the body of the instrument to engage the cutting mechanism. The instrument blade transects the seal up to 2mm from the tip of the jaws.
 19. Open the jaws by squeezing the white movable handle until it unlocks, then push it completely forward.

Cleaning the Instrument During Use

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

Troubleshooting

If the energy platform displays an error warning, refer to the Alert Situations section in this IFU.

Alert Situations

Caution

- If both the handswitch and footswitch pedal were activated during the same seal cycle, then Force Triad delivers energy from the activation source it detects first.
- A pulsed tone will sound when an alert condition occurs, and the LigaSure touchscreen on the Force Triad 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

If this message appears, the user should:

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

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

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- *Regrasp thicker Tissue – 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 metal objects, such as staplers, 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; Minimize fluids.

Endpoint Not Reached

If this message appears the user should:

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

Storage and Handling

- Temperature: -18° C to 60° C.
- Do not expose to relative humidity above 90%.

Voltage

For use with a maximum voltage of 288 Volts (peak).

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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 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.

LigaSure Impact™, ForceTriad™, TissueFect™, LigaSure™, LigaSmart™ are trademarks of Tyco Healthcare Group.

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