A Performance Comparison Between Reprocessed and New Covidien LigaSure™ 5mm Blunt Tip Laparoscopic Sealer/Divider (1637)
The Stryker Sustainability Solutions Reprocessed LigaSure™ 5mm Blunt Tip Laparoscopic Sealer/Divider (LF1637) is a bipolar electrosurgical instrument intended for use with the ForceTriad™ Energy Platform in general (including urologic, vascular, thoracic, and thoracoscopic) and gynecologic laparoscopic surgical procedures where ligation and division of vessels and lymph is desired. The instrument creates a seal by application of RF electrosurgical 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.1

This evidence report outlines the extensive testing performed to demonstrate substantially equivalent functional performance of Reprocessed LigaSure™ 5mm Blunt Tip Laparoscopic Sealer/Divider (LF1637) in comparison to the Original Manufacturer’s (OM) device, which has not been reprocessed. Wide-ranging bench-top tests were conducted to validate the following functional attributes:

- Vessel burst pressure
- Thermal spread and jaw temperature
- Blade and jaw functionality
- Electrical resistance and safety
- Overall device reliability and functionality

Electrical Resistance and Safety

Electrical resistance testing is performed to verify that each device provides a continuous conductive pathway, ensuring proper functionality during each seal. This is performed as part of the manufacturing process, where each device (100%) is tested as part of the in-line inspection criteria.

Dielectric withstand testing is also performed on each device (100%) to ensure integrity of the electrical wire insulation. The customized testing apparatus and test method follows industry-accepted criteria referenced in the electrical safety standard, IEC 60601 (Medical Electrical Equipment Standard), published by the International Electrotechnical Commission. Dielectric withstand testing is important to not only ensure each device functions as intended after reprocessing, but that it is safe to use on the patient, as well as safe to handle by the clinical user.

References

1. VSD EL10029 Rev. A 04-2015 RM702135 - Instructions For Use - SSS Reprocessed LigaSure™ Blunt Tip Laparoscopic Sealer/Dividers (Model LF1637)
3. Reports on File. (T14398, T14336)
To demonstrate the Reprocessed LF1637 device’s ability to safely and reliably seal a wide range of vessels, including those larger in diameter, testing was conducted using porcine carotid and iliac vessels, ranging in size from 2-7mm diameter.

The Reprocessed LF1637 devices were compared to OM LF1637 devices in order to evaluate substantial equivalence of functionality between the two test groups. During the testing, vessels were first sealed and cut, followed by pressurizing the vessel by infusing with saline until the vessel ruptured, while measuring and recording peak pressure. Before the vessel burst, the maximum internal vessel pressure was determined using a customized burst pressure fixture.

Vessel burst pressure results were required to demonstrate substantial equivalency, or better than the OM device. Larger (elevated) internal vessel pressures indicate a stronger seal. A Mann-Whitney Test was used to analyze the median distribution comparison between the groups, which demonstrated significance with a p-value greater than (> 0.05, indicating the distribution’s medians were not statistically different, and therefore, no statistical difference between the two groups.

<table>
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<tr>
<th>Device Type</th>
<th>N</th>
<th>mmHg</th>
<th>P value</th>
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<td>Reprocessed (RP) LF1637</td>
<td>59</td>
<td>519.4</td>
<td>0.1112</td>
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<tr>
<td>OM LF1637</td>
<td>30</td>
<td>391.7</td>
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Table 1. Vessel Burst Pressure Results Summary

Lateral thermal damage can occur as a result of protein denaturing in tissue, when sealing temperature reaches above 60°C (140°F). This is a critical functional attribute to consider when advanced energy devices are activated near vital organs and structures, especially when used in a wide range of procedures.

Porcine carotid and iliac vessels, ranging in diameters from 2mm to 7mm, were used to evaluate the distance of thermal spread of tissue after a complete seal for both reprocessed and OM devices. Infrared thermal images were recorded using an infrared camera. An infrared camera along with customized fixturing and validated software were employed to capture, calculate, and analyze the maximum distance from the middle of the device jaws to where the tissue surrounding the jaws reached a temperature that would result in protein denaturation in tissue (> 60 °C (140°F)).

Additionally, maximum jaw temperature testing was performed to evaluate the maximum temperature of the device jaw component during sealing of porcine carotid and iliac vessels ranging from 2-7mm diameter. Infrared images of each device’s thermal footprint was recorded with a FLIR Infrared Camera using customized fixturing and analyzed using a customized, mathematical software program. Acceptance criteria dictated that the maximum jaw temperature during a complete seal cycle shall be equivalent to or less than the OM.

For both test methods, a total of N=29 OM samples were compared to N=59 reprocessed samples and were evaluated using a Mann-Whitney test for significance. Both reprocessed and OM samples performed substantially equivalent to each other when comparing medians, with p-values greater than (> ) 0.05, indicating the distribution’s medians were not statistically different.
As part of the manufacturing process for Reprocessed LF1637 devices, the cutting blade and some distal tip subassembly components are removed and discarded during disassembly of the device prior to the other device components entering the decontamination and cleaning steps. These are replaced with brand new, equivalent components during reassembly of the device, prior to in-line function testing. The specifications (geometries, dimensional tolerances, material, etc.) of these replacement components were derived through reverse engineering the OM devices, and therefore, are designed to be substantially equivalent to those originating in an OM device.

As part of the validation activities performed to prove substantial equivalency of the components, the replacement blade and distal tip sub-assembly components underwent extensive testing, in comparison to an OM device. The following evaluations were performed, and have met the established acceptance criteria based on bench-top testing data of an OM device:

- **Cut quality** - This test evaluated the quality of a cut made by the replaced blade.
- **Blade deployment** - This test evaluated the distance that the blade travels within the jaw assembly when the blade trigger is fully engaged.
- **Blade trigger force** - This test assessed the forces required to engage the blade trigger.
- **Blade trigger force through media** - This test assessed the forces required to engage the blade trigger when the blade is cutting through media.
- **Jaw opening angle** – This test evaluated the angle between the upper and lower jaws when the jaw is completely open.
- **Force to open jaws** - This test assessed the forces required to open the jaws.
- **Jaw clamp force** – This test assessed the forces that are translated through the shaft of the device to the jaws when the jaw trigger is engaged.

Figure 5. Jaw force testing on the Instron (close-up)  
Figure 6. Jaw force testing on the Instron
In order to demonstrate overall device reliability and functionality of the Reprocessed LF1637 device, extensive simulated clinical cycle testing was performed, where each reprocessed device was cycled through 120 simulated-use actuations, intended to exceed a typical clinical use.

Each device was then evaluated to confirm the following critical functional attributes:

- **Seal cycle completion**
  - Appropriately sized vessels/tissue is adequately sealed.
  - Device provides audible feedback for the cautery button activation.

- **Blade deployment**
  - When jaws are closed, blade deploys and retracts to normal position
  - When jaws are open, blade is not deployed (safety mechanism)

- **Grasping mechanism**
  - Device provides audible and tactile feedback for the jaw locking/unlocking function
  - Jaw release mechanism of grasped vessel/tissue when handle is unlocked

- **Unintended electrical energy transmission does not occur through various feature combinations when activation button is:**
  - activated, jaws are either open or closed (locked), and no vessel/tissue is grasped.
  - not activated, jaws are either open or closed (locked), and no vessel/tissue is grasped.
  - not activated, jaws are either closed (locked), and vessel/tissue is grasped.

- **Cable connection and generator recognition**
  - Cable inserts into generator as intended and remains securely connected to the ForceTriad during use.
  - Device is recognized by the ForceTriad Generator software version 3.50 or greater.
  - Jaw rotation
  - User can rotate jaws when jaw trigger is unlocked.

- **Compatibility with trocar accessory**
  - Device can be inserted and withdrawn through the cannula of a 5 mm trocar, as intended.
  - Force required to insert a device through a 5mm trocar is measured.

Additional testing was performed on the rotator knob and handle lock mechanisms:

- **Rotator Knob**
  - Testing was performed to assess forces required to rotate the rotator knob throughout its entire range of motion, in addition to the amount of rotation (measured through linear displacement) that is possible throughout the entire range of motion.

- **Handle Lock/Unlock Force**
  - Testing was performed to assess the forces required to engage/disengage and lock/unlock the jaw trigger.