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Stryker's reprocessed LigaSure Impact without Nano-coating Large Jaw, Open Sealer/Divider (LF4418): **a preclinical comparison to Medtronic's LigaSure Impact Curved, Large Jaw, Open Sealer/Divider (LF4318)**

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Abstract: In recent years the goal of achieving the "Triple Aim" has put pressure on healthcare providers to simultaneously decrease healthcare costs while still providing high quality care. For clinicians, preferred devices are oftentimes more expensive. Third party reprocessing reduces some of the tension between cost and preference by offering more affordable versions of popular devices. Additionally, FDA-regulated single-use device (SUD) reprocessing reduces medical waste. The benefits of cost and waste reduction will not be realized if the reprocessed (RP) devices are not able to consistently perform as safely and effectively as the original equipment manufacturer's (OEM) devices.
Stryker's Sustainability Solutions (Stryker) division has been setting the standard for third party reprocessing and remanufacturing SUDs for over 20 years. With the introduction of the reprocessed LigaSure Impact without Nano-coating Large Jaw, Open Sealer/Divider (RP LF4418), a financially and environmentally friendly option of an industry leading direct energy device is now available. The purpose of this study is to evaluate the safety and performance of our RP device as compared to the Medtronic device (LF4318), which is the non-coated version of the LigaSure Impact.

Introduction: Backed by 18 years of clinical use, the LigaSure Impact has been a trusted and valued product in the operating room for open procedures requiring hemostasis. Offering improved visibility, enhanced usability and more intuitive access and positioning, the LigaSure Impact is the gold standard for advanced direct energy in open procedures. These devices have been vital to providing excellent hemostasis and efficient transection of vascular structures (vessels, tissue bundle and lymphatics) through the application of bipolar electrosurgical energy.
Through the process of disassembly, cleaning, remanufacturing, function testing, packaging and sterilization, we have enabled an additional clinical use of the RP LF4418. Through in vivo preclinical testing and ex vivo benchtop testing, our devices were rigorously compared to Medtronic's devices, where they were found to be statistically equivalent across all measures.

Methods: The performance of our RP LF4418 was meticulously compared to the Medtronic LF4318 through **1)** an acute porcine study (seal integrity, tissue sticking, cutting quality and thermal spread), **2)** an acute lymphatics study (lymphatic sealing capability using a methylene blue dye for visualization), **3)** a 21-day chronic animal study (long-term seal quality, hemostatic complications and thermal injury to adjacent tissues) and **4)** benchtop testing (vessel burst pressure, maximum jaw temperature and device reliability).

Results: Preclinical testing in an in vivo acute study revealed statistically equivalent performance in seal integrity, tissue sticking and cut quality when comparing the Stryker and Medtronic devices. Our device demonstrated adequate lymphatic sealing capabilities and histopathology results for all arteries, AV bundles and veins analyzed. Histological results demonstrated thermal spread maximum width (5.21mm $\bar{x}$, Stryker; 4.73mm $\bar{x}$, Medtronic) and maximum length (2.85mm $\bar{x}$, Stryker; 2.62mm $\bar{x}$, Medtronic) to be statistically equivalent between the Stryker and Medtronic devices. Pathological clinical observation following a 21-day in-life chronic study identified effective long-term seal quality, and no indication of hemostatic complications or post-operative adjacent thermal damage for the Stryker instrument. Ex vivo benchtop studies further revealed statistically equivalent performance in comparing vessel burst pressure, maximum jaw temperature and reliability testing after simulating a worst-case clinical scenario of extended instrument utilization.

Conclusion: Rigorous preclinical studies and ex vivo bench testing demonstrate that Stryker RP LigaSure Impact devices (LF4418) are at least as safe and effective as Medtronic original LigaSure Impact devices (LF4318).

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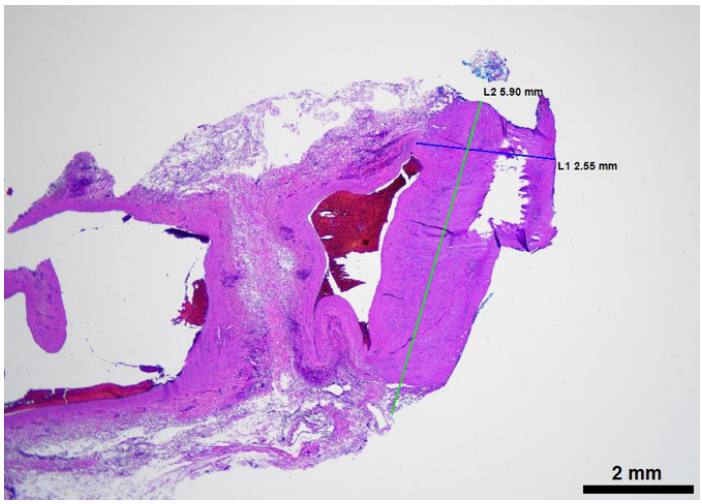
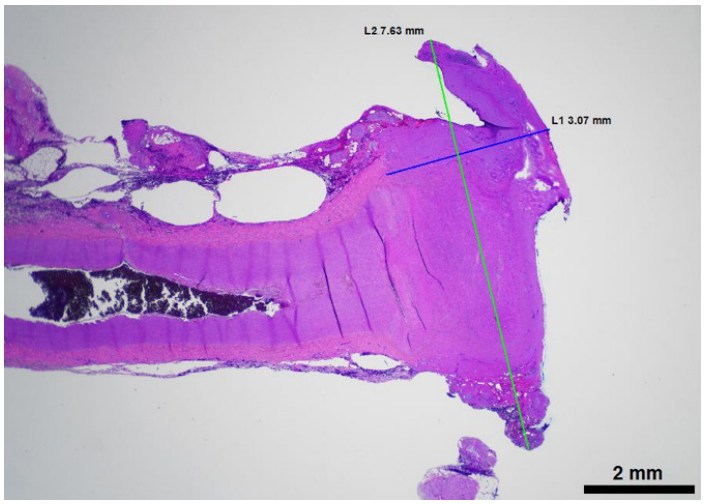
Pre-clinical testing:[3,4,5]

Following the execution of acute and chronic pre-clinical studies approved by the Institutional Animal Care and Use Committee (IACUC), surgeon and pathologist assessments found no statistical difference in any attribute amongst our devices and Medtronic devices. Safe performance for our Stryker model was demonstrated through consistent vascular sealing performance, absence of adjacent tissue damage and lack of collateral thermal damage.

Across two acute GLP porcine model studies, over 162 seals/cuts were completed utilizing Stryker test instrument surgeries, which were then measured against 163 seals/cuts from Medtronic. Subsequent to a ventral laparotomy, various physiological structures were rated on a four-point scale by a surgeon for seal integrity, tissue sticking and cutting quality.† The depth and lateral thermal spread of vessels excised post-procedure were also compared via histomorphometry (53 Stryker seals, 57 Medtronic seals) utilizing Hematoxylin and Eosin (H&E) methods. The Stryker



Stryker RP LF4418



Medtronic LF4318

Figure 1: Thermal spread: representative histological images

	Mean thermal spread (width)	Mean thermal spread (length)	Seal integrity	Tissue sticking	Cut quality
Stryker LF4418	5.21mm (N=53)	2.85mm (N=53)	1, (N=102)	1, (N=102)	1, (N=60)
Medtronic LF4318	4.73mm (N=57)	2.62mm (N=57)	1, (N=103)	1, (N=103)	1, (N=60)

Table 1: Pre-clinical acute animal study results and ratings

†The 4-tiered scale used for each evaluation is as follows:
Seal integrity: 1 = "Seal at tissue site, no leakage of blood (complete hemostasis)"; 2 = "Seal at tissue site, slight oozing of blood that stops within (≤) 1 min."; 3 = "Partial sealing of vessel, brisk bleeding present that requires intervention"; 4 = "Incomplete sealing with uncontrolled bleeding requiring intervention". **Tissue sticking**: 1 = "No sticking, tissue falls off instrument when opened"; 2 = "Tissue sticking, minor adherence to one or both jaws"; 3 = "Tissue sticking requiring counter tension and extensive force to remove tissue"; 4 = "Tissue sticking such that tissue is damaged or torn during the removal process". **Cut Quality:** 1 = "Adequately performs a complete dissection"; 2 = "Multiple attempts required to dissect intended tissue"; 3 = "Failure to perform tissue dissection".

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Vessel type	Vessel identification
A/V Bundle	Splenic mesentery, gastrosplenic, short gastric, right and left ovarian pedicle, bowel mesentery, uterine bundle, omentum, broad ligament
Artery	Splenic, right and left renal, large intestinal, right and left carotid
Vein	Splenic, right and left renal, large intestinal, right and left internal and/or external jugular
Lymphatics	Mesenteric lymph node, thoracic lymph duct

Table 2: Vessels targeted for pre-clinical acute and chronic testing

device consistently demonstrated effective lymphatic fusion and minimal thermal damage across a range of vessel types and sizes up to seven millimeters in diameter.

In a chronic GLP porcine model study, a long-term survival study (21 days) was initiated following a splenectomy, unilateral nephrectomy and ovariohysterectomy. Six procedures were performed with our devices and one with the Medtronic device. Upon completion of the study period, hemostasis was reconfirmed. Additionally, gross necropsy findings showed no presence of active hemorrhages, collateral structure damage or injury.

Ex vivo benchtop testing:[6]

The ability for our RP LF4418 to deliver hemostatic seals capable of withstanding a hypertensive crisis was assessed through a supraphysiological burst pressure test system using porcine carotid and iliac arteries. Burst pressures from ex vivo testing were statistically equivalent for the Stryker devices (511.8 mmHg $\tilde{x}$) and Medtronic devices (475.8 mmHg $\tilde{x}$). Incorporating a worst-case clinical use scenario of 78 activation cycles further highlighted the performance capabilities of our device over time. Elevated burst pressure evaluations following the 78th activation cycle indicated reprocessed burst pressure functionality (696.3 mmHg $\tilde{x}$) to be statistically equivalent to performance at zero time (T=0). Of importance to note is that burst pressure for all seals for both Stryker and Medtronic devices exceeded the industry accepted supraphysiological burst pressure threshold of 240 mmHg[7,8].

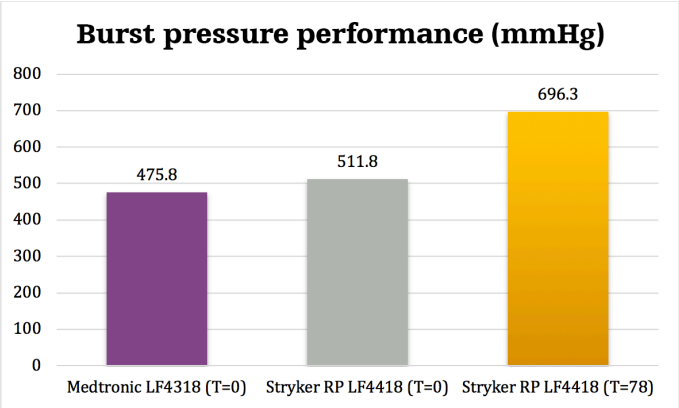

Figure 2: Burst pressure performance over time

Finally, maximum jaw temperatures were evaluated utilizing a thermal imaging Forward Looking Infrared Radiometer (FLIR) A655sc IR camera during device activation on porcine carotid and iliac arteries. Analysis of the infrared thermal videos was carried out using custom Matlab programming reading and reporting maximum temperatures observed on the LigaSure Impact device jaws. No significant differences were noted when comparing 59 Stryker RP LF4418 jaw temperatures (27.392 ˚C $\tilde{x}$) to 30 Medtronic LF4318 jaw temperatures (30.250 ˚C $\tilde{x}$).

Conclusion:

These studies demonstrate that the Stryker RP LigaSure Impact (LF4418) effectively seals while maintaining equivalent temperature profiles and minimizing thermal damage. Similarly, the FDA has deemed our RP LF4418

to be substantially equivalent, or as safe and effective, as Medtronic's LF4318, as evidenced by their granting of a 510(k) clearance[9].

References:

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