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Stryker's reprocessed LigaSure Blunt Tip (LF1637): **a preclinical comparison to Medtronic's LigaSure Blunt Tip (LF1637)**

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Abstract: Hospitals are facing increasing pressures to decrease the cost of care while delivering high quality clinical outcomes. One area where hospitals can impact their bottom line is adopting a single-use medical device (SUD) reprocessing program. Reports estimate that physician preference items (PPIs) constitute anywhere from 40% to 60% of a hospital's total supply costs[1]. The LigaSure Blunt Tip Sealer/Divider is one of these PPIs. By offering a substantially equivalent version of Medtronic's LigaSure Blunt Tip Sealer/Divider (LF1637), Stryker's Sustainability Solutions (Stryker) is providing hospitals with a more environmentally sustainable and cost-effective way to offer the same high-quality outcomes.

Introduction: The LigaSure 5mm Blunt Tip Sealer/Divider (LF1637) is a bipolar electrosurgical instrument with an intended use for minimally invasive or open surgical procedures wherein ligation and division of vessels, tissue bundles and lymphatics is desired. The instrument utilizes radio frequency (RF) energy to seal vessels and a surgeon actuated blade to divide vessels up to and including 7mm in diameter[2]. The device has a variety of applications including urological, vascular, thoracic and gynecological specialties[3].

Stryker is the global leader in third party SUD reprocessing. SUD reprocessing is the practice of disassembling, cleaning, function testing and sterilizing previously used medical devices for another approved clinical use. In the U.S., SUD reprocessing is regulated by the Food and Drug Administration (FDA). For class II SUDs such as the LF1637, third-party SUD reprocessing companies like Stryker typically demonstrate that their reprocessed devices are at least as safe and effective as legally marketed predicate devices by obtaining a 510(k) clearance from the FDA prior to introducing the reprocessed device to the market[4]. The value that healthcare providers will gain is a clinically preferred device at a lower cost that reduces the amount of waste their facility produces.

Methods: This study compares the performance of Medtronic's LigaSure Blunt Tip Sealer/Divider (LF1637) to Stryker's reprocessed Blunt Tip Sealer/Divider (LF1637) in **1)** benchtop testing (vessel burst pressure, maximum jaw temperature and reliability), **2)** acute animal studies (seal integrity, tissue sticking, cut quality and thermal spread) and **3)** chronic (21 day) animal studies (long term seal quality, presence of hemostatic complications and thermal injury to adjacent tissues). These studies resulted in no statistically significant differences in performance between the Medtronic and Stryker devices.

Results: Ex vivo benchtop studies revealed statistically equivalent performance in comparing vessel burst pressure, maximum jaw temperature and reliability testing after 334 activation cycles. An acute animal study found our devices to be statistically equivalent to Medtronic devices, regardless of vessel size, across multiple metrics including seal integrity, tissue sticking and cut quality.

Additionally, both mean maximum thermal spread depth (2.44mm - Stryker; 2.37mm - Medtronic) as well as mean maximum thermal spread width (5.26mm – Stryker; 5.22mm – Medtronic) of the Stryker devices were statistically equivalent to Medtronic devices. The chronic study demonstrated effective long-term seal quality, no indication of acute post-operative or active bleeding and an absence of hemostatic complications at 21 days. Additionally, there was no evidence of thermal injury to the adjacent tissues attributed to the use of either Stryker or Medtronic devices.

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Ex vivo benchtop testing:

Vessel burst pressure

The vessel burst pressure test assessed seal strength under fluid pressure. Benchtop vessel burst pressure testing was performed ex-vivo to provide a consistent setup for a variety of vessels sizes and types and to allow for a more controlled, direct comparison between Medtronic and reprocessed devices. A total of 89 vessels were sealed and perfused with saline at a constant rate of 2.5ml/min until leakage occurred. Thirty vessels were sealed with Medtronic devices and 59 vessels were sealed with Stryker's reprocessed devices. The maximum pressure prior to breach was recorded for each vessel sealed. Median burst pressures for Medtronic (388.84 mmHg) and Stryker (481.47 mmHg) were statistically equivalent. Of importance to note is that burst pressures for all seals from Stryker's reprocessed devices exceeded the industry-accepted supraphysiological burst pressure threshold of 240 mmHg[5,6].

Maximum jaw temperature

Maximum temperatures were recorded utilizing a Forward Looking Infrared (FLIR) A655sc IR camera. A custom MATLAB script was then used to analyze image sequences of the surgical device during activation. Thirty Medtronic devices and 59 Stryker reprocessed devices were used to record a total of 89 jaw temperature measurements. Mean jaw temperatures for Medtronic devices (82.29°C) and Stryker devices (80.91°C) were found to be statistically equivalent.

Reliability testing

To determine whether device functionality declines as activation cycles increase, a total of 23 Stryker reprocessed Blunt Tip (LF1637) devices were used to take seal and cut measurements for an evaluation of burst pressure after 334 cycles on porcine vessels. A median burst pressure value of 497.34 mmHg for carotid arteries was measured after the 334th activation cycle, which was found to be statistically equivalent to a median seal strength of 481.47 mmHg for vessels measured after the 1st cycle. As these burst pressure values are indicative of seal strength, burst pressure data demonstrates that the device can reliably seal after 334 cycles.

Acute animal study

Study design

To assess clinical performance for Stryker's reprocessed LigaSure Blunt Tip Sealer/Divider, thermal spread, tissue dissection, tissue sticking and lymphatic seal integrity – hemostasis were evaluated. The studies were performed using Institutional Animal Care and Use Committee (IACUC) approved protocol on porcine models. A surgeon performed a ventral laparotomy and ventral neck cutdown with each animal having multiple arteries, veins and artery/vein bundles sealed and dissected in three (3) test animals and three (3) control animals. One device was used per animal, either a control or a test device. Each device was used to perform 20-25 cuts/seals and 20-25 dissections per animal. Vessels of different sizes and with various physiological features were specifically targeted for the study (Table 1). Seal integrity (at one minute), tissue sticking and cut quality were rated on a three to four-point scale by the surgeon after performing each incision†. To eliminate bias, the surgeon, pathologist and clinical staff were blinded to the device manufacturer (Medtronic versus Stryker's reprocessed devices) until after all scoring, measurements and gross evaluations were completed.

Vessels sealed during the procedure were excised. The study pathologists analyzed samples to assess thermal damage and histomorphometry as a means of measuring thermal spread. Two types of measurements were made on each sealed vessel—maximum length of thermal spread (depth, measured longitudinally along vessel) and the maximum width of thermal spread (lateral spread).

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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 1: Vessels targeted for pre-clinical testing

	Mean thermal spread (width)	Mean thermal spread (depth)	Seal integrity-hemostasis (1-4)†	Tissue sticking (1-4)†	Cut quality (1-4)†
Stryker	5.26mm N=67	2.44mm N=67	1, N=74 2, N=1	1, N=72 2, N=3	1, N=60
Medtronic	5.22mm N=69	2.37mm N=69	1, N=69	1, N=66 2, N=2 3, N=1	1, N=42

Table 2: Acute animal study results and ratings

†The 3 or 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, but slight oozing of blood that stops within defined time"; 3= "Partial sealing of vessel, but 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"
Dissection cut quality: 1= "Adequately perform a complete tissue dissection"; 2= "Multiple attempts required to dissect through intended tissue"; 3= "Failure to perform tissue dissection"

Study results

Histopathology: both the Stryker and Medtronic devices performed safely without imparting damage to adjacent tissue structures. There was no gross or microscopic evidence of ongoing hemorrhage at the sealed sites, demonstrating consistent vascular sealing with both the test and control devices. Importantly, there was also no notable collateral thermal damage during necropsy. Results of additional animal study parameters appear in Table 2. There was no statistical difference between the Medtronic and Stryker devices on any of the attributes in Table 2.

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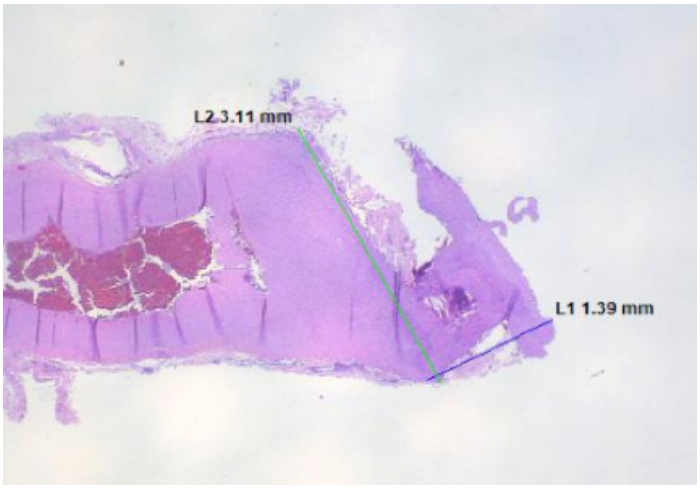

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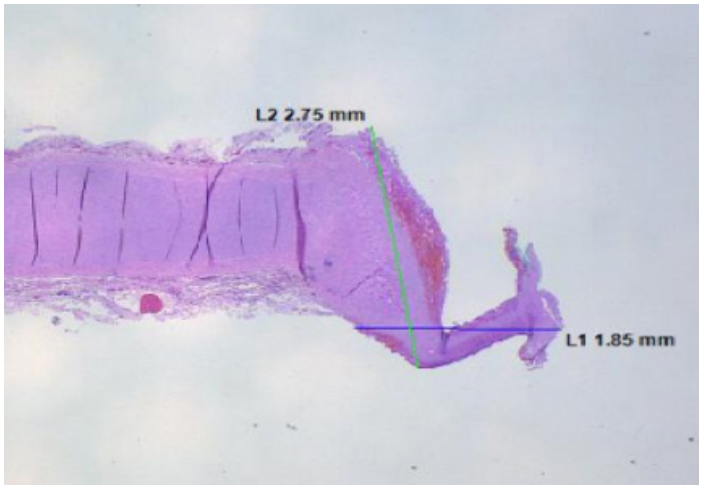

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Figure 1. Thermal spread: representative histological images

Chronic animal study

A 21-day survival study assessed long-term seal quality and potential for injury to adjacent tissue structures. A ventral laparotomy was performed in this porcine study prior to undergoing splenectomy, unilateral nephrectomy and bilateral oophorectomy. The study group was comprised of six (6) Stryker devices used on six (6) animals, and the control group was comprised of one (1) Medtronic device used on one (1) animal. All devices were used in accordance with the instructions for use, and all animals survived the duration of the study.

A necropsy was performed at 21 days for gross examination and to assess hemostasis of sealed vessels. In the Stryker study group, a total of 81 vessels were sealed. No complications related to the surgical procedure were noted. An absence of anemia in addition to the normal clinical findings suggest that seal integrity remained sufficient throughout the in-life phase of the study. All vessels were successfully sealed and remained sealed throughout the duration of the study. The study revealed no findings suggestive of notable hemorrhage surrounding treatment and control sealed vessel sites, nor was there grossly apparent injury to any collateral structures from either the Stryker or Medtronic devices.

Discussion

Acute and chronic animal studies, as well as rigorous benchtop testing demonstrate that Stryker Reprocessed Blunt Tip (LF1637) devices perform as effectively as Medtronic Blunt Tip (LF1637) devices. Certain factors drive device functional performance equivalency between Stryker and Medtronic devices. One factor is that the generators (ForceTriad, FT10), as opposed to the actual device, modulates the energy delivered to the device during use. A key component in delivering consistent performance is the actual reprocessing and testing sequence for the Stryker devices. For effective cleaning and to facilitate multi-point inspections on each component, the Stryker devices are disassembled into various levels. Each component assembly must

meet pre-determined acceptance criteria if it is to be used in a final product. Each blade is replaced to ensure adequate cutting quality. Reassembled devices then undergo rigorous, simulated-use testing, including mechanical and electrical performance evaluations. Only devices that pass all criteria are commercially released for clinical use, which serves to control for performance variability amongst our devices.

Conclusion:

As indicated by the 510(k) clearance, FDA has determined that Stryker's reprocessed LigaSure Blunt Tip Sealer/Dividers (LF1637) are substantially equivalent to predicate devices manufactured by Medtronic[7]. The ex vivo benchtop, acute and chronic animal studies presented in this paper validate that the functional and pre-clinical performance of the Stryker reprocessed Blunt Tip device is statistically equivalent to the Medtronic Blunt Tip device.

References:

1. Definitive Healthcare (2017). https://blog.definitivehc.com/reigning-in-hospital-supply-costs-and-physician-preference-item-spending
2. FDA 510(k) Premarket Notification K130744 LigaSure 5 mm Blunt Tip Laparoscopic Sealer/Divider
3. https://www.medtronic.com/covidien/en-us/products/vessel-sealing/ligasure-blunt-tip-sealer-divider.html
4. 21 CFR Part 807, Subpart E, FDA Premarket Notification Procedures (2016)
5. Chen J, Jensen CR, Manwaring PK, Glasgow RE, "Validation of a laparoscopic ferromagnetic technology-based vessel sealing device and comparative study to ultrasonic and bipolar laparoscopic devices," Surgical Laparoscopy, Endoscopy & Percutaneous Techniques 27(2):e12-e17 (2017)
6. Welling AL, Scoggins PJ, Cummings JF, Clymer JW, Amaral JF, "Superior dissecting capability of a new ultrasonic device improves efficiency and reduces adhesion formation," Global Surgery 3(1):1-5 (2017)
7. FDA 510(k) Premarket Notification K172856 Reprocessed LigaSure Blunt Tip Laparoscopic Sealer/Divider

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