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Stryker's reprocessed LigaSure Maryland Jaw Sealer/Divider (LF17XX): a preclinical comparison to Medtronic's LigaSure Maryland Jaw Sealer/Divider (LF17XX)

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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 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 Maryland Jaw Sealer/Divider is one of these PPIs. By offering a substantially equivalent version of Medtronic's LigaSure Maryland Jaw Sealer/Divider (LF17XX), Stryker's Sustainability Solutions (Stryker) is providing hospitals with a way to offer the same high-quality outcomes at an increased value.

Introduction: The LigaSure Maryland Jaw Sealer/Divider is designed to be a multifunctional device that utilizes radio frequency (RF) energy to cut and seal vessels up to 7mm in diameter[2]. The key features include a combination of curved jaw (Maryland dissector), tissue grasper, cold scissors and one-step vessel sealer[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 Maryland Jaw, third party SUD reprocessing companies like Stryker must objectively 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 Maryland Jaw Sealer/Divider (LF17XX) to Stryker's Reprocessed LigaSure Maryland Jaw Sealer/Divider (LF17XX) in **1) benchtop** (vessel burst pressure, maximum jaw temperature, reliability), **2) acute animal studies** (seal integrity, tissue sticking, cut quality, thermal spread) and **3) chronic** (21 day) animal studies (long term seal quality, presence of hemostatic complications, 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 438 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 as well as mean maximum thermal spread width 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.

Conclusion: Rigorous preclinical studies and ex vivo bench testing demonstrate that Stryker reprocessed LigaSure Maryland Jaw devices are at least as safe and effective as Medtronic original LigaSure Maryland Jaw devices.

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Ex vivo benchtop testing

Vessel burst pressure

The vessel burst pressure test assessed seal strength under fluid pressure. To simulate in-vivo application, vessels were heated to 37 C° prior to sealing. A total of 129 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 99 vessels were sealed with Stryker devices. The maximum pressure prior to breach was recorded for each vessel sealed. Median burst pressures for Medtronic (739 mmHg) and Stryker (668 mmHg) were statistically equivalent. 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[5,6].

Maximum jaw temperature

Maximum temperatures were recorded utilizing a Forward Looking Infrared (FLIR) A655sc IR camera. Image sequences of the surgical device during activation were then analyzed using a custom MATLAB script. A total of 89 jaw temperatures were recorded (59 for Stryker devices and 30 for Medtronic devices). Amongst the 89 porcine vessel samples, mean jaw temperatures were statistically equivalent, recorded at 86.80° C for Medtronic and 89.1° C for Stryker.

Reliability testing

A total of 45 Stryker Maryland Jaw devices were evaluated for burst pressure after 438 cycles on porcine vessels to determine whether device functionality declines as activation cycles increase. Seal strength of carotid arteries measured after the 438th activation cycle (median value of 620.5 mmHg) were statistically equivalent to burst pressures recorded after one (1) activation cycle (median value of 777.8 mmHg), demonstrating the device can reliably seal after 438 cycles.

Acute animal study

Study design

To assess clinical performance for the Stryker Maryland Jaw device, hemostasis, thermal spread, tissue dissection, tissue sticking, and lymphatic seal integrity 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 test animals and two control animals. One device was used per animal, either a control or a test device. Each device was used to complete 25-35 cuts/seals and 10-20 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 manufacturer 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 was performed to measure 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).

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 Renal, Left Renal, Large Intestinal, Right and Left Carotid
Vein	Splenic, Right Renal, Left Renal, Large Intestinal, Left and right internal and/or external Jugular

Table 1: Vessels targeted for preclinical testing

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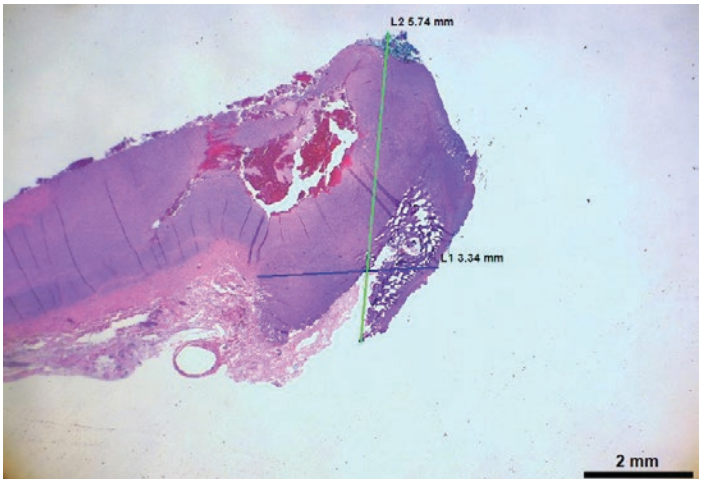
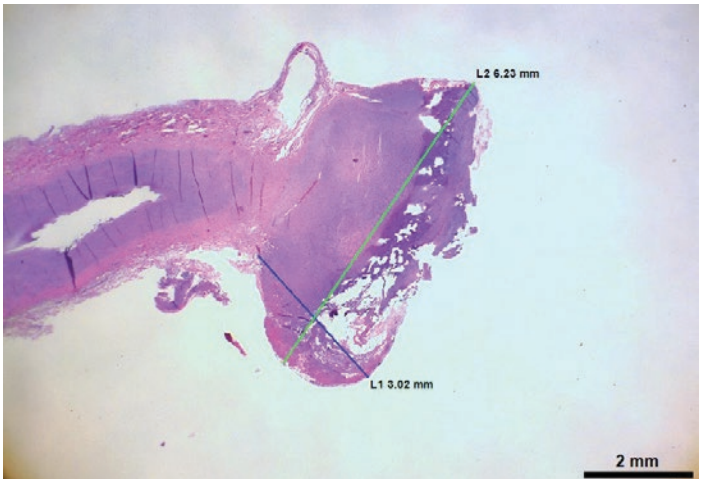
	Mean thermal spread (width)	Mean thermal spread (depth)	Seal integrity Hemostasis (1-4)†	Tissue sticking (1-4) †	Cut quality (1-4) †
	Mean thermal spread (width)	Mean thermal spread (depth)	Seal integrity - Hemostasis (1-4)†	Tissue sticking (1-4)†	Cut quality (1-4)†
Stryker	5.33mm, N = 77	2.27mm, N = 77	1, N = 93 4, N = 1	1, N = 91 2, N = 3	1, N = 30
Medtronic	5.25mm, N = 58	2.48mm, N = 58	1, N = 69	1, N = 66 2, N = 3	1, N = 30

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"



Stryker reprocessed LF1737



Medtronic LF1737

Figure 1. Thermal spread: representative histological images

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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Chronic animal study

A 21-day survival study assessed long-term seal quality and potential for injury to adjacent tissue structures. In this porcine study, a ventral laparotomy was performed prior to undergoing splenectomy, unilateral nephrectomy and bilateral oophorectomy. The study group was comprised of six Stryker devices used on six animals and one Medtronic device used on one animal in the control group. 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 94 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 Maryland Jaw devices perform as effectively as Medtronic Maryland Jaw devices. Certain factors drive parallel device performance 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 re-sharpened 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 Maryland Jaw Sealer/Dividers (LF17XX) 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 Maryland Jaw device is statistically equivalent to the Medtronic Maryland Jaw device.

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