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Stryker's Sustainability Solutions Reprocessed LigaSure Curved, Small Jaw, Open Sealer/Divider (LF1212A) and Remanufactured Exact Dissector, Without Nano-Coating (LF2019):

Pre-Clinical Comparison for Thermal Spread to OM LigaSure Curved, Small Jaw, Open Sealer/Divider and Exact Dissector, With Nano-Coating

Authors

Allen Jayaraj, MEng.
Senior Engineer, Research & Development

Kailey Stafseth, BS, MSc
Marketing Manager

Tom Kraby, MEng.
Principal Engineer, Quality Assurance

Scott English, BS
Principal Regulatory Affairs Specialist

Testing facility and clinical staff

American Preclinical Services (APS)
8945 Evergreen Boulevard NW
Minneapolis, MN 55433

Dr. Kristin Wise, DVM
Clinical Veterinarian

Dr. Muhammad Ahsan, DVM
Pathologist Report Author

Dr. Lynette Philips, DVM
Pathologist- Necropsy Assessments

Amy Puetz, BS
Quality Assurance

Nick McCune, BS
Quality Assurance

Study summary

Stryker's Sustainability Solutions (SSS) reprocessed/remanufactured LF2019 and LF1212A devices were compared to the original manufacturer (OM) devices and **found to perform as well as OM devices for thermal spread in an acute study.** Thermal spread measurements were found to be statistically equivalent between OM and SSS devices using histopathology methods. The average thermal spread depth for reprocessed LF1212A devices was 2.53mm, and 2.37mm for OM LF1212A devices, and the thermal spread width was 4.49mm and 4.46mm, respectively. For LF2019 devices thermal spread measurements were also found to be statistically equivalent between OM and remanufactured devices using histopathology methods. The average thermal spread depth for remanufactured LF2019 devices was 4.315mm, and 4.370mm for OM LF2019 devices. For thermal spread width the average was 2.07mm and 2.02mm, respectively.

Background

Advanced directed energy vascular sealing instruments have become essential with the proliferation of endoscopic procedures as well as general surgical procedures. These devices are of vital importance to providing hemostasis while sealing and dividing vessels. **With over two decades of reprocessing experience, Stryker's Sustainability Solutions is the market-leading provider of reprocessing services for medical devices.** Reprocessing of single use medical devices must demonstrate substantial equivalence. "Substantial equivalence" to a legally marketed (predicate) device is demonstrated through Premarket Notification, or 510(k) clearance, in accordance with the Food and Drug Administration (FDA) Code of Federal Regulations (21CFR Part 807).[1] Specifically, FDA draft guidance for bipolar electrosurgical vessel sealers suggests that comparative thermal spread data should be provided that includes quantitative measurement (under magnification) of the size (depth and width) of the thermal damage zone. A passing result is defined as no statistical difference between SSS reprocessed/remanufactured and OM devices.

Methods

The preclinical studies consisted of American Preclinical Services (APS) approved protocols using a porcine model.[2,3] The anatomy and physiology of the porcine model provided a tissue response to electrosurgical instrumentation similar to that of human tissues. The surgeon and pathologist were blinded as to the device identification (OM vs. SSS) until after all measurements and gross evaluation were completed to eliminate bias.

The acute animal study was designed to compare four (4) subject animals and three (3) control animals, where a total of seven (7) porcine test systems were used for the LF1212A model study. For the LF2019 model study three (3) subject animals and three (3) control animals for a total of six (6) porcine test systems were used. One reprocessed/remanufactured device was used for each subject animal and one OM device was used for each control animal. Each animal underwent procedures to seal multiple vessels of different sizes and with various physiological functions as indicated in Table 1. Device performance was assessed through thermal spread measurement.

Vessel type	Vessel identification
A/V bundle	Ovarian pedicle, short gastric, splenic, uterine bundle
Artery	Carotid, gastric splenic, large intestinal, rectal, renal, small mesenteric, splenic
Vein	Gastric splenic, internal jugular, large intestinal, rectal, renal, small mesenteric, splenic

Table 1. Vessel type and identification

Thermal spread depth and thermal spread width were measured postoperatively and evaluated by an APS board-certified veterinary pathologist. As seen in Figure 1 the thermal spread depth (indicated by the double headed arrow) was measured as the distance from the outside or outer edge of the thermal injured tissue/seal (indicated by the dotted arrow) to the endpoint of thermal change (indicated by the broken arrow). The measurements were obtained from the intimal, medial or adventitial surface of the blood vessel or vascular plexus.

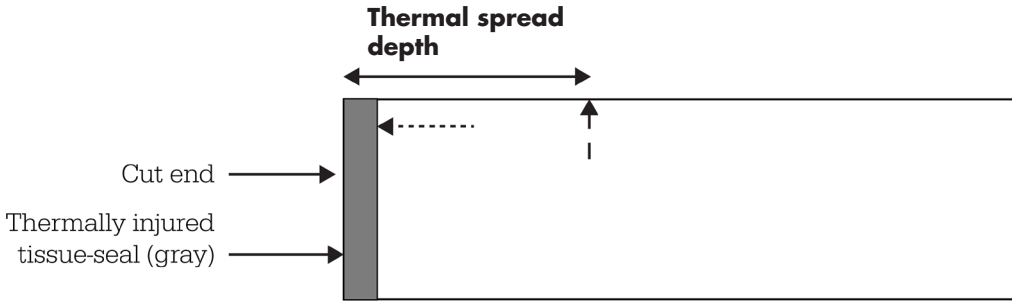

Figure 1. Depth of thermal spread measurement

The width of thermal spread (indicated by the double-headed arrow) in Figure 2 was the measured distance from the thermally injured perivascular tissue on one side of the vessel (light gray area) to the thermally injured tissue on the opposite side of the vessel. The measurement was obtained at approximately halfway between the inner edge of the thermal seal and the endpoint of the thermal injury.

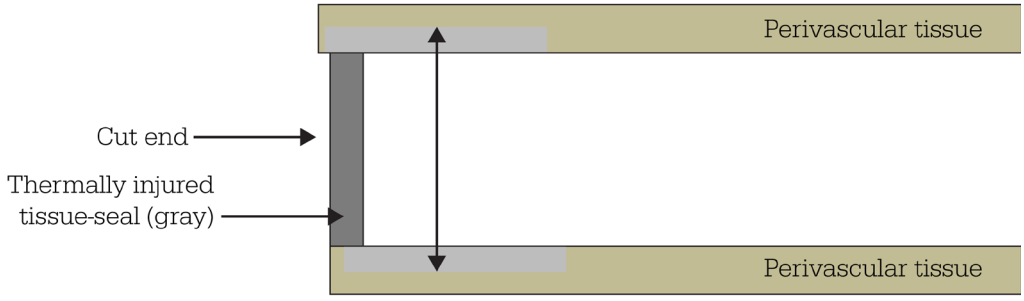

Figure 2. Width of thermal spread measurement

When comparing the data sets between OM and reprocessed/remanufactured devices for thermal spread depth and thermal spread width, statistical methods such as a two-sample t-test or Mann-Whitney comparison test was used to see if the data sets were different. When utilizing one of these statistical methods for comparison between the data sets, a p-value greater than 0.05 indicates that there is not a detectable statistical difference between populations; thus, showing equivalence between the OM and reprocessed/remanufactured devices.

Results

The intended use for the Ligasure LF1212A and LF2019 devices are vessels (arteries and veins) up to and including seven (7) mm. Table 2 and Table 3 below gives the summary of all the vessels sealed during the acute study for the LF1212A and LF2019 devices. Table 4 shows the vessel size distribution was statistically equivalent between what the SSS devices sealed vs. what the OM devices sealed.

Vessel size	LF1212A test arteries sealed	LF1212A test veins sealed	LF1212A test AV bundles sealed	LF1212A OEM arteries sealed	LF1212A OEM veins sealed	LF1212A OEM AV bundles sealed
1mm	0	2	6	2	0	8
2mm	8	2	4	1	2	6
3mm	1	10	7	7	6	6
4mm	4	3	10	4	5	3
5mm	10	7	5	6	2	6
6mm	8	3	3	5	3	3
7mm	3	2	4	4	2	6

Table 2: LF1212A sealed vessels size distributions (acute study)

Vessel size	LF2019 test arteries sealed	LF2019 test veins sealed	LF2019 test AV bundles sealed	LF2019 OEM arteries sealed	LF2019 OEM veins sealed	LF2019 OEM AV bundles sealed
1mm	0	4	5	1	4	1
2mm	4	1	7	6	3	7
3mm	5	4	8	5	7	8
4mm	9	6	9	4	4	2
5mm	6	3	9	14	4	9
6mm	3	2	0	2	7	6
7mm	1	1	2	0	1	2

Table 3: LF2019 sealed vessels size distributions (acute study)

Model	Total vessels sealed	Median (mm)	P-value	P-value > 0.05
SSS LF1212A	99	4	0.954	YES
OM LF1212A	87	4		
SSS LF2019	89	4	0.214	YES
OM LF2019	97	4		

Table 4: Vessel size distribution comparison between SSS vs. OM devices during acute study

For thermal spread width and thermal spread depth, one hundred and one (101) data points were able to be captured with the four reprocessed LF1212A devices used from the four subject animals; while eighty-five (85) data points were obtained from the three OM LF1212A devices used for the three animals assigned for those OM devices. Meanwhile for the LF2019 model study, eighty-eight (88) data points were able to be captured with the three reprocessed/remanufactured LF2019 devices used from the three subject animals; while ninety-four (94) data points were obtained from the three OM LF2019 devices used for the three animals assigned for those OM devices. Each **specimen was microscopically measured (morphometry) by the pathologist and the data was sent to the study sponsor for statistical analysis per the protocol. There was no statistical difference between the OM and reprocessed/remanufactured populations for either thermal spread depth or thermal spread width** as the p-values were greater than 0.05 as stated in Table 5. All statistical analysis can be found in SSS internal reports.[2,3]

Device	Total samples (N)	Thermal spread depth (mm)	P-value: thermal spread depth	Thermal spread width (mm)	P-value: thermal spread width	Results
SSS LF1212A	101	2.45	0.3787	4.49	0.697	PASS: Statistical equivalence
OM LF1212A	85	2.38		4.61		
SSS LF2019	88	4.315	0.772	2.07	0.7387	PASS: Statistical equivalence
OM LF2019	94	4.370		2.02		

Table 5: Thermal spread comparisons between SSS vs. OM devices (acute study)

Histology

Figures 3 and 4 represent the manner in which the histological slides were measured for the depth of thermal tissue spread. The figures are not meant to compare the thermal spread values or images to each other as they are different vessel types. The arrows in figure 3 and 4 point to an intact seal.

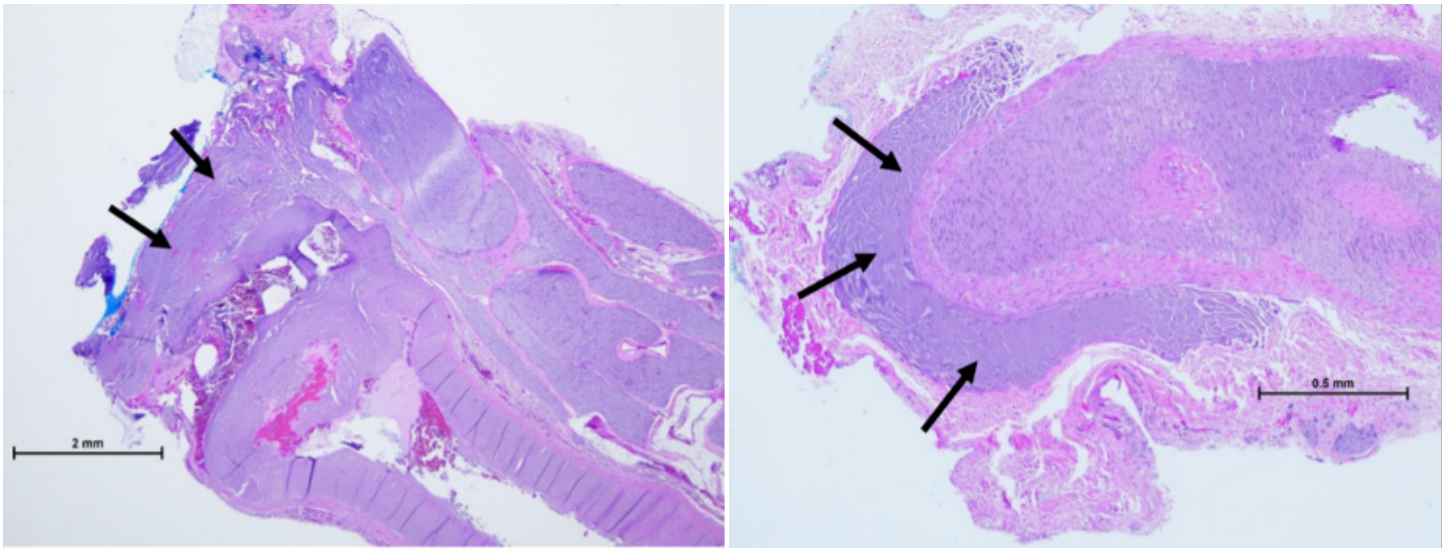

Figure 3: Reprocessed LF1212A seal on a renal artery vs. OM LF1212A on gastric artery

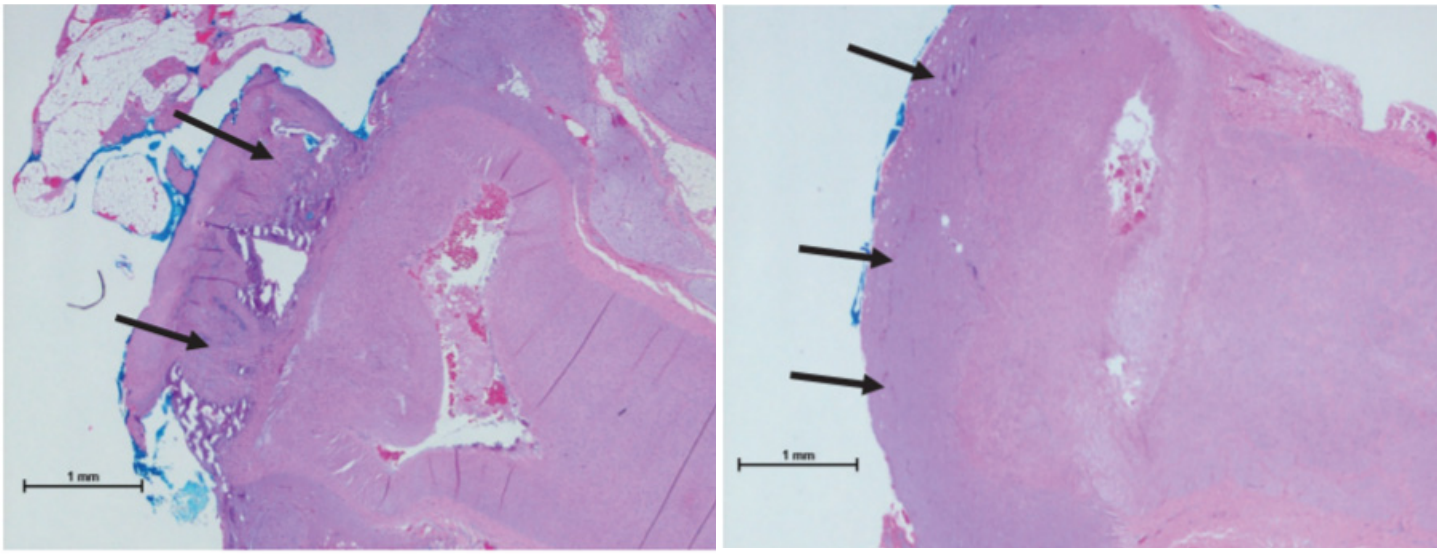

Figure 4: Remanufactured LF2019 seal on a splenic artery vs. OM LF2019 on renal artery

Conclusion

The reprocessed/remanufactured devices that compared to brand new models (OM LF1212A and OM LF2019) during the acute animal study demonstrated equivalent thermal spread measurements. This concludes that the reprocessed/remanufactured devices provide comparable spread of heat to the region in which the sealing occurred as OM devices provide. Data from these acute in vivo studies were provided as part of an FDA 510(k) pre-market notification.

References

1. 21 CFR Part 807, Subpart E, Premarket Notification Procedures.

2. Reports on file. TR20956 Engineering Study Report Design Validation Study (Acute, Chronic, and Lymphatic GLP) for Ligasure Small Jaw (LF1212A); and TR21208 Statistical Analysis for Acute Animal Study on reprocessed Ligasure Small Jaw, LF1212A

3. Reports on file. TR21190 Engineering Study Report Design Validation Study (Acute, Chronic, and Lymphatic GLP) for Ligasure Exact Dissector (LF2019); and TR21209 Statistical Analysis for Acute Animal Study on Remanufactured Ligasure Exact Dissector (LF2019)