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

A Pre-Clinical Comparison for Tissue Sticking to OM LigaSure Curved, Small Jaw, Open Sealer/Divider and Exact Dissector, Nano-Coated

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Study summary

Stryker's Sustainability Solutions (SSS) reprocessed LF1212A and remanufactured LF2019 devices were compared to the original manufacturer (OM) devices and **found to perform as well as OM devices for tissue sticking in an acute animal study. During the acute study, surgeons provided visual assessments during each sealing in the porcine system that provided a score of 1.00, which according to the scale meant no tissue sticking, as tissue falls off jaws when device is opened**. The results were comparable to the OM devices used and scored during the same study.

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 business is the market-leading provider of reprocessing services for medical devices business. Reprocessors of single-use medical devices must demonstrate "substantial equivalence" to a legally marketed (predicate) device through Premarket Notification, or 510(k) clearance, in accordance with the Food and Drug Administration (FDA) Code of Federal Regulations (21CFR Part 807)**.[1] The remanufactured exact dissector followed the exact same regulatory pathway of demonstrating substantial equivalence to a legally marketed (predicate) device through Premarket Notification, or 510(k) clearance, in accordance with 21CFR Part 807). An important aspect for reprocessed/remanufactured devices to perform equivalent to OM devices during tissue sealing is the amount of tissue sticking to the device jaws. In order to assess tissue sticking equivalence, a visual assessment is made where the surgeon is able to visually assess tissue sticking during the study per a scoring code.

Method

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. reprocessed/remanufactured) until after all scoring, 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. **Tissue sticking to jaws was used as one way to assess device performance**. Figure 1 shows the area that is visually assessed for the LF2019, same jaws area is assessed for LF1212A.

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

Figure 1. Area for tissue sticking assessment (LF2019)

A scoring code was used for the tissue sticking assessments of the tissue sticking to the jaws of the devices[‡]. Assessments were made by the surgeons during the vessel sealing procedures. Descriptive statistics comparison was done to compare the median of the scoring assessments taken from all the reprocessed/remanufactured devices, compared to the median of the scoring assessments for all the OM devices used during the procedures. The raw data and detailed statistical analysis are contained in the report on file[2,3].

Results

As stated previously, the intended use for the LigaSure LF1212A and LF2019 devices are vessels (arteries and veins) up to and including 7mm. Table 2 and Table 3 below gives the summary of all the vessels sealed during the acute study for the LF1212A and LF2019 devices.

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)

When comparing LF1212A devices, one hundred and two (102) reprocessed data points and seventy-four (74) OM data points were evaluated for tissue sticking by the surgeon when performing sealing on the vessels. While eighty-nine (89) data points were obtained for remanufactured LF2019 devices, and ninety-seven (97) data points for OM LF2019 devices. **Overall average for both the reprocessed/remanufactured and OM ranking for tissue sticking was 1.00 indicating no tissue sticking as tissue falls off the device when opened. Descriptive statistics comparison was done, and it yielded no difference in the mode or median for the tissue sticking assessments.** All statistical analysis can be found in SSS internal reports[2,3].

Conclusion

The reprocessed/remanufactured devices that compared to brand new models (OM LF1212A and OM LF2019) during the acute animal study demonstrated comparable tissue sticking scores. The overall assessment indicated that there was no tissue sticking as the tissue fell of the jaws when opened. This demonstrates that the reprocessed/remanufactured devices provide no greater risk to tissue sticking than the OM devices. Data from these acute and chronic in vivo studies were provided as part of an FDA 510(k) pre-market notification.

‡ The 4-tiered scoring code used for the visual assessments were as follows:

Evaluation	Scoring code
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

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)