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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):

A Blade Sharpness and Effectiveness of Reprocessed LigaSure Curved, Small Jaw, Open Sealer/Divider and Remanufactured Exact Dissector, Without Nano-Coating

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Study summary

The Stryker's Sustainability Solutions (SSS) reprocessed LF1212A and remanufactured LF2019 devices are intended for use in open surgical procedures where ligation and division of vessels, tissue bundles and lymphatics is desired. The instruments can be used on vessels (arteries and veins) up to and including 7mm.

Blade sharpness is of high importance for the safety and effectiveness of the LF1212A and LF2019 devices. Two of the many goals for products of SSS are the reduction of landfill waste and cost savings for customers. Having little to no refurbishment or replacement of components reduces material waste and adds to these cost savings. Through a process of thorough verification and validation methods, Stryker's Sustainability Solutions business has proven that the LF1212A and LF2019 perform as safely and effectively as the original manufacturer (OM) devices without the need for replaced or refurbished blades.

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. Stryker's Sustainability Solutions business is the market-leading provider of reprocessing for medical devices. SSS offers innovative, cost-effective programs to meet the resource management demands of its hospital partners, while reducing the environmental impact, to support advancements in responsible healthcare.

Method

Blade sharpness verification has been performed using benchtop testing called reliability testing. Furthermore, blade sharpness verification will be performed through in-line testing on each reprocessed/remanufactured unit. A summary of testing is as follows:

Reliability verification

Reliability testing is a multi-step process that consists of the reprocessed/remanufactured devices undergoing one hundred and thirty (130) seal/cuts on beef tripe to simulate the maximum usage cycles of the devices. The maximum usage value was found from a survey that was conducted with over one hundred surgeons[1]. The maximum cuts answered for both LF1212A and LF2019 devices was one hundred (100). Adding a safety factor to this value, a total of one hundred and thirty one (131) seal/cuts was the number used for the number of seal/cuts on beef tripe to perform during the reliability testing. After simulated usage the reprocessed/remanufactured devices perform cuts on high-density polyethylene (Tyvek), where each cut is inspected to assure no bunching or fraying is observed. This would prove the blades still provide sharp cuts even after undergoing maximum usage.

In-line verification

SSS will perform two in-line blade sharpness verification steps on 100% of reprocessed LF1212A and remanufactured LF2019 devices. The first step will be visual inspection of the blades under magnification, in which the images must show no blade degradation, rust or debris for the device to pass through the rest of production. The second step will be a cut test in which each device is used to cut a piece of Tyvek. The device must be able to perform a cut on the Tyvek paper in which no bunching or fraying is observed on the Tyvek near the cuts. Feasibility and verification testing have yielded a relatively high number of devices that passed the in-line visual, and Tyvek cut tests. This can be attributed to the soft tissue procedure indications for these devices, which include urologic, thoracic, plastic and reconstructive.

Results

As part of design verification from two different studies, approximately one hundred and twenty-one (121) reprocessed LF1212A and remanufactured LF2019 devices have undergone reliability testing. All devices that went through the Tyvek cut test after the reliability testing showed acceptable cuts.[2,3] An example of an acceptable cut is shown in Figures 3 and 4.

During production, blade inspection is performed by exposing the device blades and visually inspecting them under magnification. Figure 1 displays a sample image of an OM LF1212A blade on the left compared to a reprocessed LF1212A blade on the right. Figure 2 displays an OM LF2019 blade on the left and a remanufactured LF2019 blade on the right. As demonstrated by these images, any degradation to the blades would be obvious in the production visual inspection.

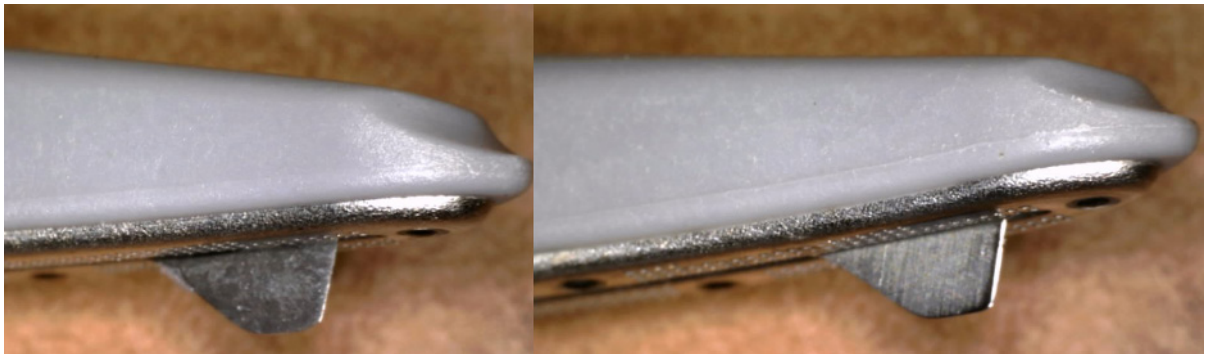

Figure 1. OM LF1212A blade vs. reprocessed LF1212A blade under magnification

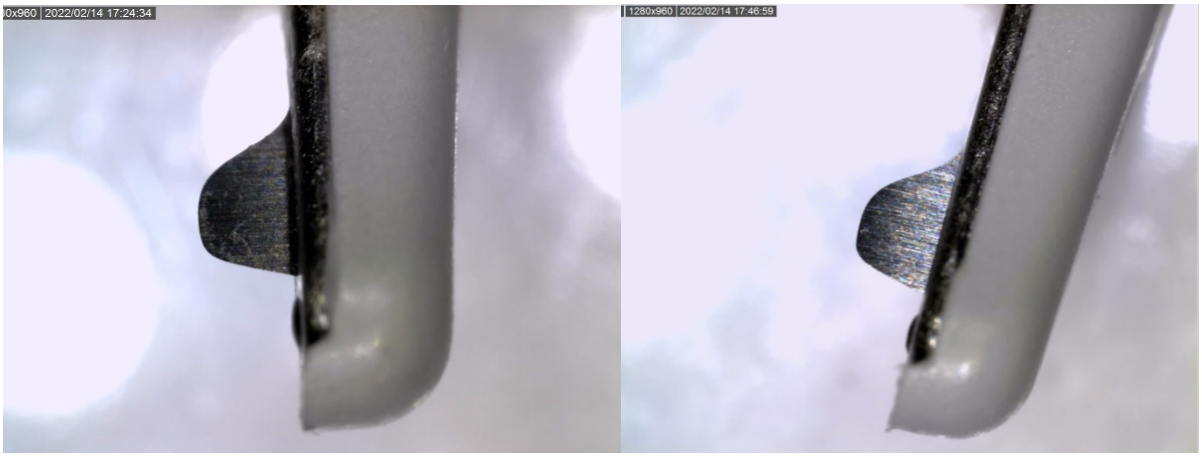

Figure 2. OM LF2019 blade vs. remanufactured LF2019 blade under magnification

In the blade cut quality in-line inspection test (Tyvek cut test), each device is mechanically actuated to demonstrate a cut through Tyvek paper. Figure 3 demonstrates a Tyvek cut test performed by an OM LF1212A device on the left, as compared to a reprocessed LF1212A device on the right. Figure 4 demonstrates Tyvek cuts made by OM LF2019 device on the left, as compared to a remanufactured LF2019 device on the right. As demonstrated by Figure 3 and Figure 4, any degradation in cut quality will be obvious during in-process inspection.

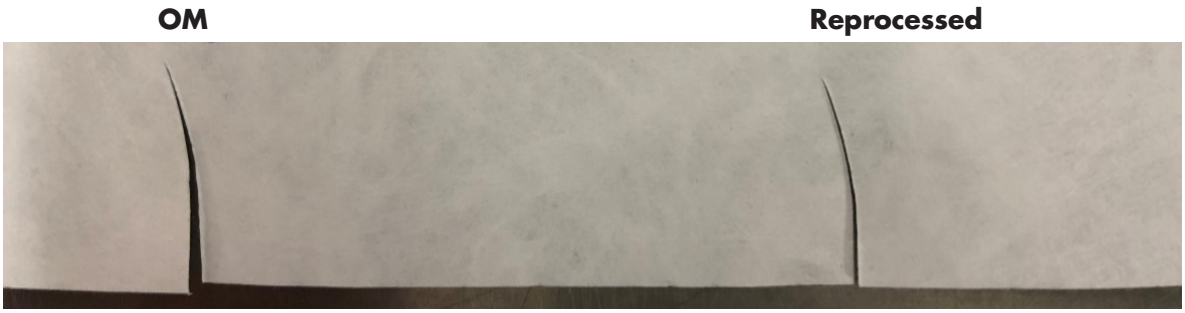

Figure 3. OM LF1212A cut (left) vs. reprocessed LF1212A cut

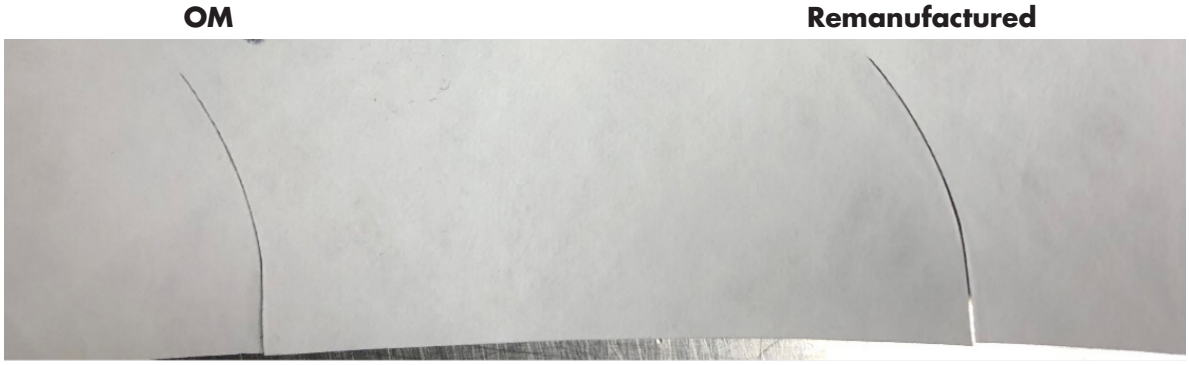

Figure 4. OM LF2019 cut (left) vs. remanufactured LF2019 cut

Conclusion

All reprocessed/remanufactured devices that have gone through the simulated maximum usage, then put through the Tyvek cut test, have passed. Production processes screen all devices using a visual inspection (Figure 1 and 2) and a cut quality (Tyvek cut) test (Figures 3 and 4) to further verify blade sharpness. Through pre-market verification testing and production inspection, we ensure that all reprocessed LigaSure Curved, Small Jaw, Open Sealer/Divider (LF1212A) and remanufactured LigaSure Exact Dissector, Without Nano-coating (LF2019) devices contain blades that are sharp, safe and effective.

References

1. Report on file. DHFD15687 NPD Small Jaw (LF1212A & LF2019) Clinical Survey from GLG Report on file.
2. Report on file. TR20908 Functional Performance Report for Covidien LigaSure Small Jaw Open Sealer/Divider (LF1212A)
3. Report on file. TR21173 Functional Performance Report for Covidien LigaSure Exact Dissector without Nano-Coating (LF2019)