Reprocessing/Remanufacturing **overview**

stryker

Reprocessed LigaSure™ Curved, Small Jaw, Open Sealer/Divider (LF1212A) and Remanufactured LigaSure™ Exact Dissector, Without Nano-coating (LF2019)

Decontamination and cleaning: Our reprocessed/remanufactured tissue sealer/divider devices are initially inspected for visible damage. Devices found with visible damage or gross contamination are rejected immediately. Every device then undergoes a multi-step cleaning process that involves blade pre-treatment and full device cleaning through submersion.

1. Devices are submerged in pretreatment chemical to mitigate rust within the devices.
2. Devices are then submerged in proprietary cleaning chemicals to clean devices of biologics and debris.
3. Synergies have been identified within our cleaning lines to optimize the use of water and unnecessary chemicals.

No replacement components: Verification and validation activities performed prove the cleaning process and overall device effectiveness is achieved without replacement components. This further achieves cost savings for customers and reduces component waste.

Performance testing: Every tissue sealing device is functionally tested using electrical testing, blade inspection to ensure cutting performance and blade Tyvek cut test for blade sharpness inspection.

Visual inspection: All tissue sealer/divider devices are inspected throughout various steps of the production process to ensure non-conforming products are rejected. Devices are inspected for debris, contamination, and for overall device integrity. A magnification system is also utilized for blade inspection to ensure cutting performance.

Device tracking: Each tissue sealing device is labeled with a barcode on the handle and marked for reprocessing/remanufacturing cycles to ensure the device is never reprocessed/remanufactured beyond its maximum number of cleared cycles. Upon receipt, all quantities of approved devices are scanned into a device tracking system and recorded.

Packaging: Reprocessed/remanufactured LigaSure tissue sealer/divider devices are packaged individually in our unique packaging design, consisting of the peeling pouch, mounting card and corrugated shipping box. Compared to OEM packaging, we have reduced the packaging weight by 41%, for the reprocessed LF1212A device, and 13% for the remanufactured LF2019 device. The packaging is also able to be recycled within typical hospital streams. Finally, our LigaSure Small Jaw and Exact Dissector devices are packaged in case quantities equivalent to the original equipment manufacturer and distributed for sale.

Ethylene oxide exposure: The ethylene oxide (EO) sterilization process is validated according to the requirements in ANSI/AAMI/ISO 11135. The EO sterilization validation demonstrates the process and equipment are capable of consistently and reliably achieving a minimum of a twelve (12) spore log reduction (SLR). This equates to a sterility assurance level of 10^{-6}. The EO residuals do not exceed the maximum allowable limits per ANSI/AAMI/ISO 10993-7 for both adult and pediatric populations. This confirms the product is sterile and safe for patient use.

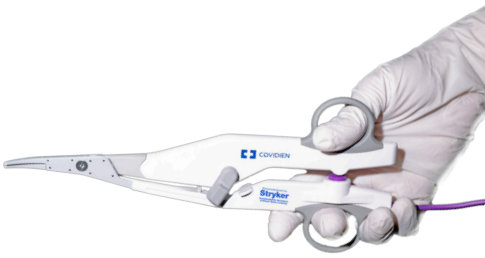
Auditing the process: Routine quality control audits are completed to ensure process integrity. Reports are provided to senior management for operating line performance and control. Additionally, finished product performance attributes, including cleaning end points, are routinely subjected to random sampling and inspection.

Documentation: Production support staff are required to sign off after performing each reprocessing/remanufacturing step. Detailed documentation ensures traceability of critical steps performed. Records are maintained in accordance with FDA and ISO requirements.

Product summary

- Our reprocessed/remanufactured tissue sealer/divider devices include the following models: LigaSure Curved, Small Jaw, Open Sealer/Divider (LF1212A) and Remanufactured LigaSure Exact Dissector, Without Nano-coating (LF2019) originally manufactured by Medtronic Covidien.
- Our devices are Redesigned for Sustainability™ to reduce packaging, metal and plastic, along with water and chemical waste.

LF1212A



LF2019

Sustainability Solutions 1 888 888 3433 sustainability.stryker.com

MKT10352 REV A 2214 | Stryker, 1810 West Drake Drive, Tempe, AZ 85283 USA | 888 888 3433 | Copyright © 2022 Stryker