Reprocessing **overview**

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Reprocessed LigaSure Blunt Tip without Nano-coating, 37cm Laparoscopic Sealer/Divider (LF1837), Reprocessed LigaSure Impact without Nano-coating Large Jaw, Open Sealer/Divider (LF4418) and Reprocessed LigaSure Maryland Jaw, Open and Laparoscopic Sealer/Divider without Nano-coating (LF1923, LF1937and LF1944)

Decontamination and cleaning: Our reprocessed LigaSure tissue sealer devices are initially inspected for visible damage. Devices found with visible damage or gross contamination are rejected immediately.

For the LigaSure Blunt Tip (LF1837):

- Every device is disassembled to facilitate cleaning of jaws and internal components
- Shaft insulation, cutting blades, guides, wires, activation pins and associated jaw components are removed from the device and rejected/discarded (sent for material recycling)

For the LigaSure Impact (LF4418) and Maryland Jaw (LF1923, LF1937 and LF1944):

- Every device is disassembled to facilitate cleaning of jaws and internal components
- Shaft assemblies remain intact throughout the reprocessing operation to maintain the blade mechanism
- Plug halves, RFID tags and OM Aztec labels are removed from the device and rejected/discarded (sent for material recycling)

Next, all LigaSure device's (LF1837, LF4418 and LF19XX) remaining individual components undergo a multi-step cleaning process, with chemistries compatible with materials of construction and effective in removing residual soil and debris to predetermined acceptable endpoints.

Device reassembly with replacement components: Once the cleaning and visual inspection processes are complete, replacement components that have been reverse engineered/sourced from a third party and validated as substantially equivalent to new (OM) components are introduced during device reassembly.

LigaSure Blunt Tip (LF1837) replacement components include:

- Laparoscopic cutting blade
- Blade guide weldments
- Wire guide
- Jaw pin
- Blade activation pin (to ensure like-new cutting ability)

LigaSure Impact (LF4418) and LigaSure Maryland Jaw (LF1923, LF1937 and LF1944) replacement components include:

- Cord
- Plug
- RFID tag
- Aztec code labels (to ensure like-new performance)

All LigaSure device reassembly includes lubrication of mechanical component interfaces, soldering of electrical connections, and robotic solvent bonding of handle halves.

Performance testing: Every tissue sealing device is functionally tested for electrical safety and performance (including dielectric withstand testing) in accordance with IEC 60601-1 and 60601-1-2.

Product summary

Our reprocessed tissue sealer/divider devices include the following models:

- Reprocessed LigaSure Blunt Tip without Nano-coating, 37cm Laparoscopic Sealer/Divider (LF1837)
- Reprocessed LigaSure Impact without Nano-coating Large Jaw, Open Sealer/Divider (LF4418)
- Reprocessed LigaSure Maryland Jaw, Open and Laparoscopic Sealer/Divider without Nano-coating (LF1923, LF1937 and LF1944) originally manufactured by Medtronic Covidien

LF1937

100% of LigaSure devices undergo mechanical performance testing to ensure full articulation and proper function of the rotator knob, jaw trigger and blade triggers.

To ensure optimal cutting performance of the replaced blades, an industry standard cut test is completed on all devices.

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.

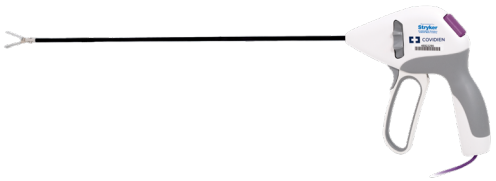
Device tracking: Each tissue sealing device is labeled with a barcode on the handle and marked for reprocessing cycles to ensure the device is never reprocessed beyond its maximum number of cleared cycles. Upon receipt, all quantities of approved devices are scanned into a device tracking system and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

Packaging: Reprocessed LigaSure devices are packaged individually in our blister packs (also known as thermoformed trays with a heat sealed Tyvek® lid) creating a Sterile Barrier System. Tyvek® is made from HDPE (High Density Polyethlene) and does not allow the ingress of microbes. Finally, our LF1837, LF4418, LF1923, LF1937 and LF1944 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 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 step. Detailed documentation ensures traceability of critical steps performed. Records are maintained in accordance with FDA and ISO requirements.



Blunt Tip

Impact

Maryland Jaw

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