Product Availability: Reprocessed LigaSure™ devices are distributed to customers in case quantities of six (same as the original manufacturer).

Decontamination and Cleaning: LigaSure™ devices accepted through the receipt and sorting process are disassembled using proprietary custom fixtures. Each device component is subjected to a decontamination and cleaning process that includes the use of enzymatic cleansers and disinfection agents compatible with all device materials. The heat shrink tubing is removed from each device and replaced during re-assembly. The jaws are disassembled with a laser etching process and the original blade is discarded. Elements are disinfected and devices undergo multiple rinses to remove any remaining chemicals. After components are thoroughly cleaned, they are placed in a custom vacuum drying chamber to extract any residual moisture. The devices then undergo inspection for damage and non-conforming parts. Stryker’s standards are based on AAMI TIR30, a series of processes, materials, test methods and acceptance criteria for cleaning medical devices.

Product Summary:
- Includes model LF1637 originally manufactured by Covidien.
- Used in general and laparoscopic procedures on vessels and lymphatics up to and including 7mm and tissue bundles.
- Intended for use with the ForceTriad™ Energy Platform where ligation and division of vessels and lymph is desired.
**Inspection, Reassembly and Performance Testing:** LigaSure™ components are first inspected under microscopy and magnification to ensure each component meets Stryker’s strict acceptance criteria. Stryker technicians inspect every component for damage and non-conformance with quality standards. Parts are subject to testing to ensure functionality.

A brand new blade is placed within the jaw of the device. The inner and outer shafts are laser welded together with the new blade, followed by application of new heat shrink tubing to the shaft. Jaw wires are mated to the appropriate cord wires and then soldered together to create the electrical circuit. Each internal element is placed in its appropriate position and biocompatible lubrication is applied to ensure the trigger operates smoothly. The handle is fused back together with a biocompatible adhesive.

After reassembly, all devices undergo in-line performance testing including turning of the rotation knob, locking and unlocking the jaw, pulling the blade trigger and cut testing the blade.

Additional in-line performance testing includes a proprietary tester to evaluate electrical function, including button activation, to ensure the appropriate level of energy is delivered.

**Device Tracking:** Every reprocessed LigaSure™ device is pad printed with biocompatible dye and marked with a bar code for identification. Bar codes are associated with device history reports and lot numbers.

**Packaging:** LigaSure™ devices are placed in a custom thermoformed tray, sealed, labeled and boxed in preparation for sterilization.

**Sterilization:** Ethylene oxide sterilization is validated as per ANSI/AAMI/ISO 11135 to a sterility assurance level of $10^{-6}$. Ethylene oxide residuals do not exceed maximum allowable limits of ANSI/AAMI/ISO 10993-7.