Reprocessing **overview**

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Reprocessed HARMONIC FOCUS® Shears with Adaptive Tissue Technology (HAR9F)

Decontamination and cleaning:
Our reprocessed HARMONIC FOCUS® Shears are initially inspected for visible damage. Devices found with visible damage or gross contamination are rejected immediately. Every device is disassembled to facilitate cleaning of blades, jaws and internal components. Used tissue pads are removed from the shears and rejected/discarded (sent for material recycling).

Each remaining individual component then undergoes a multi-step cleaning process with proprietary cleaning chemicals, compatible with materials of construction. These chemicals are effective in removing residual soil and debris to predetermined acceptable endpoints.

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:
The rods of all reprocessed HAR9F Shears are impedance tested to ensure full functionality.

100% of devices undergo generator testing to verify proper electrical function of each device. the test also ensures that replacement torque wrenches correctly attach the device to the OM handpiece and devices are appropriately recognized by the generator.

The reprocessed HAR9F Shears are powered on and tested at both MIN and MAX energy settings.

Every device is mechanically tested for proper function and articulation of the clamp arm, finger rings and MIN/MAX hand control buttons.

Visual inspection:
All HARMONIC FOCUS Shears are inspected throughout various steps of the production process to ensure non-conforming products are rejected. Devices are inspected for debris, contamination and overall device integrity.

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 HAR9F devices are packaged individually in a thermoformed tray and sealed in a film/Tyvek® peel pouch. Tyvek® is made from HDPE (High Density Polyethylene) and does not allow the ingress of microbes. Finally, our HAR9F devices are packaged in case quantities equivalent to the original equipment manufacturer and distributed for sale.

Product summary

- Our reprocessed HARMONIC FOCUS® devices include the following models: Reprocessed HARMONIC FOCUS® Shears with Adaptive Tissue Technology (HAR9F), originally manufactured by Ethicon

HAR9F

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 step. Detailed documentation ensures traceability of critical steps performed. Records are maintained in accordance with FDA and ISO requirements.

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