Reprocessing **overview**

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Reprocessed HARMONIC ACE +7 Shears with Advanced Hemostasis (HARH23, HARH36 and HARH45)

Decontamination and cleaning: Our reprocessed HARMONIC Ultrasonic 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. Tissue pads, shaft pins, trigger return springs and the coating on rods are removed from the shears and rejected/discarded (sent for material recycling).

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

Once the cleaning and visual inspection processes are complete, a new non-stick coating is applied to rods and blades. 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.

Replacement components and reassembly: Replacement components include the tissue pad, shaft pin, trigger return spring, and torque wrench to ensure like-new performance.

Reassembly includes repair of the click tab, lubrication of mechanical component interfaces, and robotic solvent bonding of handle halves.

Performance testing: The rods of all reprocessed HARMONIC Ultrasonic Shears are impedance tested to ensure full functionality and a leak decay test is performed to verify that gaskets function as intended.

100% of HARMONIC 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 shears are powered on and tested at both MIN and MAX energy settings.

Every device is mechanically tested to check for proper function and articulation of the clamp arm, rotation knob, trigger, MIN/MAX hand control buttons and advanced hemostasis button.

Visual inspection: All Ultrasonic Shears 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.

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 HARH

Product summary

- Our reprocessed HARMONIC Ultrasonic Shears include the following models: Reprocessed HARMONIC ACE +7 Shears with Advanced Hemostasis HARH23, HARH36 and HARH45, all originally manufactured by Ethicon.

HARH45

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 HARH23, HARH36 and HARH45 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.

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